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UNITED STATES DISTRICT COURT

DISTRICT OF NEW JERSEY

FRANK HALL, Individually and on)	No. 3:18-cv-01833-FLW-TJB
Behalf of All Others Similarly Situated,)	
)	<u>CLASS ACTION</u>
Plaintiff,)	
)	FIRST AMENDED COMPLAINT
vs.)	FOR VIOLATIONS OF THE
)	FEDERAL SECURITIES LAWS
JOHNSON & JOHNSON, ALEX)	
GORSKY, DOMINIC CARUSO,)	
SANDRA PETERSON, CAROL)	
GOODRICH, JOAN CASALVIERI,)	
PH.D., MICHAEL SNEED, and TARA)	
GLASGOW,)	
)	
Defendants.)	
)	<u>DEMAND FOR JURY TRIAL</u>

TABLE OF CONTENTS

	Page
I. INTRODUCTION	1
II. JURISDICTION AND VENUE	8
III. PARTIES	8
IV. RELEVANT NON-PARTIES	11
V. COMPREHENSIVE STATEMENT OF THE CASE.....	15
A. Background	15
B. The Early Years – Amidst Health Concerns Regarding Asbestos and Talc, J&J Begins Its Decades-Long Scheme to Conceal the Truth	19
1. J&J Recognizes Internally that Its Talc Is Contaminated and that It Could Lead to a Public “Furor” and Litigation	20
2. J&J Tells the Public that the Company’s Baby Powder Contains No Asbestos, but Numerous Internal Documents and J&J’s Own Efforts to Remove the Asbestos Show Otherwise.....	21
3. J&J Sets out to Influence Regulators and Purposely Avoids “Essential” Asbestos Testing Methods	25
4. J&J Monitors and Defends Against Science and Regulations.....	29
C. 1980s to 2000s – J&J Faces a New Battlefront in the War to Defend Its Flagship Product: the Association Between the Use of Talcum Powder and Ovarian Cancer	32
1. Through Falsehoods and Manipulation, J&J and Its Industry Cohorts Successfully Prevent Talc from Being Listed in the “10th Report on Carcinogens”	33

	Page
2. J&J Recognizes Internally that the “Fatal Flaw” Is an Illusion and Is yet Again Put on Notice that Its Baby Powder Is Contaminated with Asbestos	39
3. Under the Direction of Defendant Casalvieri, J&J Sets out to Keep Talc out of the 12th RoC	42
4. J&J Secretly Funds a Meta-Study Concluding that Talc Is Safe and Attempts to Influence the World Health Organization.....	44
5. Under the Direction of Defendant Casalvieri, J&J’s Efforts to Defeat the NTP Prove Successful, but J&J Fails to Manipulate IARC	48
6. J&J Is Again Warned of the Dangers Posed by Its Flagship Product	49
D. With Its Reputation on Thin Ice Because of Product Recalls and Ethical Lapses, the Company Makes Defendant Gorsky Its New CEO	53
E. The Class Period Begins – in the Face of Lawsuits Linking Its Talcum Powder to Ovarian Cancer, J&J Conceals the Company’s True Litigation Exposure and Reputational Risk	57
F. As Ovarian Cancer Litigation Spreads, Defendants Continue to Conceal J&J’s True Reputational and Litigation Exposure.....	65
G. After a Jury Finds J&J Liable for Damages in an Ovarian Cancer Lawsuit, Defendants Continue to Lie to Investors and the FDA	71
H. As J&J Is Hit with Additional Ovarian Cancer Verdicts, Defendants Continue to Conceal the Asbestos Contamination and the Company’s Longstanding Fraudulent Scheme.....	74

	Page
I. J&J Faces Its First Trial Involving Allegations of Asbestos in Talcum Powder Causing Mesothelioma	86
J. J&J Continues to Defend Its Flagship Product, but the Truth Leaks Out	89
1. September 27, 2017 Disclosure	89
2. January 30, 2018 Disclosure	94
3. February 5, 2018 Disclosure	95
4. February 7, 2018 Disclosure	98
5. Defendants Continue to Mislead Investors, as J&J Relaunches Its Baby Product Line and Defendant Peterson Unexpectedly Retires	99
6. July 12, 2018 Disclosure: J&J Is Hit with a \$4.69 Billion Talcum Powder Verdict but Claims It Was the Product of a Fundamentally Unfair Process and that J&J’s Talc Is Safe.....	104
7. December 14, 2018 Disclosure: <i>Reuters</i> Investigative Report Reveals New Information and Declares that “Johnson & Johnson Knew for Decades that Asbestos Lurked in Its Baby Powder”	108
K. The Aftermath	120
VI. DEFENDANTS’ MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS	122
A. February 2013 False and Misleading Statements	122
B. April 2013 False and Misleading Statements.....	123

	Page
C. May 2013 False and Misleading Statements.....	126
D. July 2013 False and Misleading Statements	127
E. August to November 2013 False and Misleading Statements	128
F. January 2014 False and Misleading Statements	130
G. February to October 2014 False and Misleading Statements	134
H. January to February 2015 False and Misleading Statements.....	136
I. April 2015 False and Misleading Statements.....	141
J. May to October 2015 False and Misleading Statements.....	142
K. December 2015 False and Misleading Statements	143
L. February 2016 False and Misleading Statements	148
M. May 2016 False and Misleading Statements.....	154
N. June 2016 False and Misleading Statements.....	161
O. August to November 2016 False and Misleading Statements	165
P. December 2016 False and Misleading Statements	167
Q. January 2017 False and Misleading Statements	170
R. February 2017 False and Misleading Statements	172
S. May 2017 False and Misleading Statements.....	176
T. August 2017 False and Misleading Statements	177
U. September to November 2017 False and Misleading Statements.....	180

	Page
V. January 2018 False and Misleading Statements	187
W. February to April 2018 False and Misleading Statements	189
X. May 2018 False and Misleading Statements	198
Y. July to August 2018 False and Misleading Statements	206
Z. October 2018 False and Misleading Statements	214
VII. FRAUDULENT SCHEME AND COURSE OF BUSINESS	216
VIII. ADDITIONAL SCIENTER ALLEGATIONS	216
A. Defendant Gorsky	217
B. Defendant Caruso	220
C. Defendant Goodrich	221
D. Defendant Casavieri	223
E. Defendant Peterson	225
F. Defendant Glasgow	226
G. Defendant Sneed	227
H. Additional Allegations Supporting Defendants' Scienter	228
1. Johnson's Baby Powder Was Absolutely Critical to Consumers' Trust and J&J's Overall Business and Reputation	228
2. J&J Purposely Avoided Testing Methods Capable of Finding the Asbestos in the Company's Talc and Powders	231

	Page
3. J&J Conducted a Widespread, Longstanding Fraudulent Scheme	232
4. J&J Knew of Asbestos Being Found in Its Talc and Powders and Received Numerous Red Flags	235
IX. LOSS CAUSATION/ECONOMIC LOSS	238
X. NO SAFE HARBOR	239
XI. APPLICABILITY OF PRESUMPTION OF RELIANCE: FRAUD ON THE MARKET	240
XII. CLASS ACTION ALLEGATIONS	241
XIII. CLAIMS FOR RELIEF	243
PRAYER FOR RELIEF	247
JURY DEMAND	248

I. INTRODUCTION

1. Long marketed as an ethical pillar of American business, Johnson & Johnson (“J&J” or the “Company”) has worked tirelessly over the years to build a reputation as the “Baby Company.” Inextricably intertwined with this reputation is Johnson’s Baby Powder, “one of the most familiar and trusted products in the world,” according to J&J. Considered by J&J to be a ““sacred cow,”” a ““flagship product’,” an “institution,” and “a primary link to the positive J&J name in the public mind,” Johnson’s Baby Powder symbolizes J&J’s legacy of being a “lifelong friend of the family” and has long been associated with purity and cleanliness. But hidden from the public (and investors) was the reality that Johnson’s Baby Powder was contaminated with cancer-causing asbestos – a fact that J&J concealed through a highly-organized, decades-long campaign of deceit.¹

2. Prior to and during the period from February 22, 2013 through December 13, 2018 (the “Class Period”), defendants engaged in a scheme to defraud investors and issued false and misleading statements in order to conceal the truth regarding the Company’s talc and Baby Powder. Specifically, defendants intentionally concealed that: (i) J&J’s talc and talcum powder products were contaminated with asbestos, as J&J had been repeatedly informed; (ii) J&J had attempted to find ways to remove

¹ The U.S. federal government has made clear that there is no safe level of asbestos exposure. Even trace amounts are considered dangerous.

asbestos minerals from its talc; (iii) J&J purposely avoided the use of testing methods that could detect the asbestos present in the Company's talc, and (iv) J&J had influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation.

3. During the Class Period, the Company was facing product liability litigation over its Baby Powder and the product's alleged association with ovarian cancer. As defendants knew, Johnson's Baby Powder was crucial to "the positive J&J name in the public mind" and critical to J&J's reputation as a trustworthy company. With the Company's flagship product and very identity at stake, defendants made material misstatements and omissions regarding the Company's talc and talcum powder products, its true litigation and reputational exposure, and its management and decision-making processes.

4. During the Class Period, defendants repeatedly claimed that J&J's talc products had "a long history of safe use" and promised that the products are, and always had been, free of asbestos. But while defendants claimed that the Company's cosmetic powder products have been safe "[f]or over 100 years," and that "regular testing conducted since the 1970s" had confirmed the absence of asbestos, defendants knew that J&J's talc and talcum powders had long been contaminated with asbestos. In fact, from at least 1971 to the 2000s, the Company's raw talc and finished powders repeatedly tested positive for asbestos, and Company executives, mine managers,

scientists, doctors and lawyers discussed the asbestos contamination, but failed to disclose it to regulators or the public.

5. Defendants also concealed what they recognized internally, that talc had *not* been used safely for over 100 years, that some scientific sources “could be interpreted as suggesting a causal effect” between ovarian cancer and talc, and that “[e]ven some of the studies [J&J] cite[d] send mixed messages.” And while defendants assured investors that J&J’s “talc products are, and always have been, free of asbestos,” internally J&J admitted that “*we cannot say ‘always.’*”

6. Defendants’ assurances regarding the Company’s asbestos testing were also false and misleading, as J&J’s asbestos testing “since the 1970s” had not “confirmed” that the talc or powders were “asbestos free.” While defendants represented during the Class Period that J&J used “a sophisticated battery of tests designed to ensure . . . safety,” the truth was that J&J intentionally avoided sophisticated “concentration techniques” for testing, which J&J knew were necessary for finding asbestos in talc. In fact, J&J’s own consultant had informed the Company that “larger amounts of sample” must be tested to find asbestos, and that “preconcentrat[ing] the impurities prior to examination” “was considered essential to the success of any suggested procedure.” But because J&J knew that a concentration method would show asbestos in the Company’s talc, J&J determined that the method “may be too sensitive,” leading the Company to “avoid promotion of this approach,”

as J&J “really want[ed] to exclude concentration techniques.” Indeed, when the U.S. Food and Drug Administration (“FDA”) later requested proposals for ““sophisticated”” testing techniques that would lead to “concentration procedures,” J&J found it to be ““disturbing,”” as the techniques would make “many talcs on all markets . . . hard pressed in supporting purity claims.”

7. Throughout the Class Period, defendants also misrepresented the Company’s internal policies and concealed J&J’s long history of infiltrating and undermining regulatory processes. According to defendants, J&J “has always taken questions about the safety” of Johnson’s Baby Powder “extremely seriously,” particularly because it is a product “that families have trusted for generations.” In truth, J&J had lied to the FDA about its talc and undermined the activities of certain public health officials and doctors it branded as ““Antagonistic Personalities.””

8. Rather than being “guided by the medical facts and science when it comes to [its] products,” or “always put[ting] . . . safety first in everything that [it does],” J&J has long been driven by the objective of protecting the (false) *image* of safety of Johnson’s Baby Powder. Indeed, J&J strove “to neutralize [and] hold in check data . . . generated by investigators who question the safety of talc.” And while a December 1977 – January 1978 report illustrates J&J’s knowledge that both its Baby Powder and talc contained asbestos, that same report also shows that the Company had set out “[t]o monitor and defend against consumerist, scientific and regulatory

attitudes/trends which could impact adversely on the safety image and marketability of cosmetic talcs.” Even while J&J knew that its talc and Baby Powder contained unsafe asbestos, it had nonetheless set forth on a mission “[t]o generate or provide . . . data to support and reinforce the safety of our baby powder.”

9. In September 2017, the Company faced its first trial alleging the presence of asbestos in Johnson’s Baby Powder, brought by a plaintiff-consumer with mesothelioma. On September 21, 2017, *Bloomberg* reported on documents from the 1970s that had been unsealed in the talc litigation, reporting that “J&J was alerted to [the] *risk* of asbestos in talc in [the] ‘70s.” At the same time, however, the article reported that J&J documents showed “*tests of its talc stretching back to at least 1972 found no trace of asbestos*,” and reiterated defendants’ promise that J&J’s “talc products are, *and always have been*, free of asbestos.” The *Bloomberg* article also quoted defendants as claiming that “[h]istorical testing of samples by the FDA” as well as “numerous independent” laboratories and scientists “have all confirmed the absence of asbestos in our talc products.” Defendants’ vigorous denials in the *Bloomberg* article (and throughout the Class Period) prevented investors from learning the truth and maintained inflation in J&J’s stock price. But through a series of partial disclosures the relevant truth would leak out and cause the stock price to decline.

10. For example, on February 5, 2018, investors were informed that “experts [were] anticipating the release of numerous damaging internal company documents”

from J&J relating to asbestos in its Baby Powder. The Company's stock declined over 5% in response, and numerous financial analysts and commentators attributed the decline to the news. But defendants continued to defend J&J's talc products, falsely reassuring consumers and investors once again that the products "are, and always have been, free of asbestos" and that this was shown by "'decades of monitoring, testing and regulation dating back to the 1970s.'"

11. Then, on July 12, 2018, investors were stunned when a jury awarded a \$4.69 billion verdict to 22 plaintiffs alleging that asbestos in J&J's products caused their ovarian cancer. As numerous news outlets reported, J&J's stock price dropped in response to the verdict. In order to continue their fraudulent scheme, and stem the decline in J&J's stock price, defendants claimed that the verdict "was the product of a fundamentally unfair process" in which "the evidence in the case was simply overwhelmed by the prejudice" J&J purportedly suffered.

12. Finally, on December 14, 2018, *Reuters* published a bombshell report entitled "***Powder Keg: Johnson & Johnson knew for decades that asbestos lurked in its Baby Powder***" (the "*Reuters* report"). The *Reuters* report disclosed new information and new analysis, including internal J&J documents "reported to the public for the first time." In addition to revealing J&J's knowledge of asbestos contamination, *Reuters* disclosed J&J's "successful efforts to influence U.S. regulators' plans to limit asbestos in cosmetic talc products and scientific research on

the health effects of talc.” The report also detailed how J&J had purposely avoided concentration techniques and how J&J knew that such methods could find asbestos in its talc products. In response to the *Reuters* report, ***J&J’s stock plunged 10%***, wiping away nearly ***\$40 billion in market value*** in a single day.

13. In response to the Reuters report’s revelations, the U.S. government has taken action. For example, on December 14, 2018, U.S. Senator Ed Markey requested that the FDA “immediately investigate these allegations and determine whether Johnson & Johnson’s actions have placed at risk the public’s health and safety.” On January 28, 2019, U.S. Senator Patty Murray sent J&J a letter requesting documents related to the “alleged decades-long effort by Johnson & Johnson to potentially mislead regulators and consumers about the safety” of Johnson’s Baby Powder. And, on February 20, 2019, J&J disclosed that it had received “preliminary inquiries and subpoenas” from the U.S. Department of Justice (“DOJ”) and the U.S. Securities and Exchange Commission (“SEC”) to produce documents regarding this securities class action lawsuit and the safety of its talc-containing products.

14. As a result of defendants’ conduct alleged herein, J&J’s stock traded at artificially inflated prices during the Class Period. The truth concealed by defendants’ scheme has slowly leaked out and caused economic damages to investors.

II. JURISDICTION AND VENUE

15. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Securities Exchange Act of 1934 (the “1934 Act”) (15 U.S.C. §§78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. §240.10b-5).

16. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331 and §27 of the 1934 Act.

17. Venue is proper in this District pursuant to §27 of the 1934 Act and 28 U.S.C. §1391(b). Many of the acts charged herein, including the preparation and dissemination of materially false and misleading information, occurred in substantial part in this District.

18. In connection with the acts alleged in this complaint, defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications and the facilities of the New York Stock Exchange (“NYSE”), the world’s largest stock exchange by market capitalization.

III. PARTIES

19. Lead Plaintiff San Diego County Employees Retirement Association (“SDCERA” or “plaintiff”) purchased J&J common stock during the Class Period and was damaged by the conduct alleged herein. *See* Ex. 1. SDCERA, which operates under the direction and governance of an independent Board of Retirement,

administers retirement and associated benefits for more than 43,000 active, deferred, and retired members on behalf of the County of San Diego and other participating employers.

20. Defendant Johnson & Johnson develops, manufactures, and sells health care products. According to J&J's filings with the SEC, its "primary focus is products related to human health and well-being." It has three business segments: Pharmaceutical (including its Janssen Pharmaceutica subsidiaries), Medical Devices, and Consumer (including Johnson's Baby Care products). J&J maintains its headquarters at One Johnson and Johnson Plaza, New Brunswick, New Jersey 08933. The Company's stock trades on the NYSE under the ticker symbol "JNJ."

21. Defendant Alex Gorsky ("Gorsky") is, and throughout the Class Period was, the Chairman of the Board and Chief Executive Officer ("CEO") of J&J. He has served as CEO since April 26, 2012 and Chairman since December 28, 2012. Gorsky began his career at J&J in 1988, served as Vice President ("VP") of Marketing at J&J's Janssen Pharmaceutica ("Janssen") unit from 1998 to 2001, and then as President of Janssen from 2001 to 2003. Gorsky left J&J for Novartis, Inc. ("Novartis") in 2004, but returned to J&J in 2008, serving in various leadership positions prior to being selected as CEO.

22. Defendant Dominic Caruso ("Caruso") was Chief Financial Officer ("CFO") of J&J through much of the Class Period. He became CFO in 2007, and

served as Executive VP since April 2016. On March 20, 2018, J&J announced Caruso's decision to retire in September 2018, ending his 19 year-career at J&J.

23. Defendant Sandra ("Sandi") Peterson ("Peterson") was Group Worldwide Chair at J&J from 2012 to October 2018. Known as a corporate "fixer," Peterson was brought in to fix the quality and supply chain issues that J&J had faced leading up to the Class Period. Peterson was the first outsider to ever join the Company's Executive Committee.

24. Defendant Carol Goodrich ("Goodrich") is, and throughout the Class Period was, the Director of Corporate Media Relations at J&J. Goodrich worked on the corporate webpage regarding talc on J&J's "Our Safety & Care Commitment" website in 2013 and made public statements on behalf of J&J from 2016 through 2018.

25. Defendant Joan Casalvieri, Ph.D. ("Casalvieri") was Director of Toxicology and Skincare, at J&J Consumer Inc. ("JJCI"). J&J's extensive efforts to defend talc from scientific and regulatory scrutiny in 2005 were conducted under her direction, and led to the National Toxicology Program ("NTP") withdrawing talc from consideration as a possible carcinogen. Casalvieri was featured and quoted on J&J's website in 2015.

26. Defendant Michael Sneed (“Sneed”) has been J&J’s Executive VP of Global Corporate Affairs & Chief Communication Officer since 2012. He is also a member of J&J’s Executive Committee. Sneed has worked at J&J since 1983.

27. Defendant Tara Glasgow (“Glasgow”) was VP of Research and Development (“R&D”) for the Baby franchise at J&J’s consumer division. She first joined J&J in 1994. Glasgow made public statements on behalf of J&J from 2015 through 2017.²

IV. RELEVANT NON-PARTIES

28. William (“Bill”) Ashton (“Ashton”) was a long-time employee of J&J who was deeply involved in many of the Company’s activities surrounding talc and Johnson’s Baby Powder. He was present at the Company from at least 1969 into the 2000s.

29. Sarah L. Colamarino (“Colamarino”) first joined J&J in 1989 and is currently the Company’s VP of Corporate Equity & Partnerships. She was VP of Corporate Communication from 2008 to July 2011, which included working on communications to shareholders. In 2004, Colamarino learned that Johnson’s Baby Powder tested positive for asbestos.

² The defendants identified in ¶¶21-27 are referred to herein as the “Individual Defendants.”

30. The Center for Regulatory Effectiveness (“CRE”) is an industry-funded lobbying organization. According to J&J’s long-time talc supplier, the CRE “assists mainly corporations with advice and intervention in federal regulatory issues that threaten their business,” with a staff that “is comprised mainly of former federal government officials and lawyers who understand and intervene in the regulatory system.” The CRE was pivotal in J&J and its talc supplier’s efforts to influence and manipulate the NTP.

31. The Cosmetic, Toiletry, & Fragrance Association (“CTFA”) (now known as the Personal Care Products Council) is a national trade association representing the interests of the cosmetic and toiletry industry. The CTFA has long served as a buffer for J&J’s talc-related activities.

32. The Food and Drug Administration (“FDA”) is a federal agency within the U.S. Department of Health and Human Services (“HHS”). According to the federal government’s website, USA.gov, the FDA “is responsible for protecting the public health by assuring the safety, efficacy, and security” of various products, including food, drugs, and cosmetics.

33. Dr. John Hopkins (“Hopkins”) is a toxicologist who worked for J&J from 1976 to 2000. He joined the Medical Department of J&J in 1976, eventually becoming the Head of the Department. In or around 1990, Hopkins became J&J’s

R&D Director in the United Kingdom. Most recently, he has served as the Company's corporate representative in trials related to J&J's talcum powders.

34. Imerys Talc America, Inc. ("Imerys") is the current supplier of talc to J&J. It was previously known as Luzenac America ("Luzenac") and owned by Rio Tinto Minerals ("Rio Tinto").

35. The International Agency for Research on Cancer ("IARC") is an agency of the World Health Organization ("WHO"). It reviewed talc as a possible carcinogen and concluded in 2006 that "perineal use of talc-based body powder is possibly carcinogenic to humans." Prior to that decision, J&J attempted to get its own representatives involved in the IARC review process but failed to do so. As J&J recognized internally, "[i]t is VERY difficult to have any impact on the IARC."

36. Dr. Steve Mann ("Mann") was Director of Toxicology at J&J Consumer & Personal Products Worldwide in the early 2000s. Mann was very involved in the Company's talc-related activities under the direction of defendant Casalvieri, especially with regards to the IARC and the NTP. In 2004, he was notified that an independent laboratory had found asbestos in Johnson's Baby Powder.

37. The National Toxicology Program ("NTP") is an interagency program of HHS headquartered at the National Institute of Environmental Health Sciences ("NIEHS"), and supported by NIEHS, the FDA's National Center for Toxicological Research, and the National Institute for Occupational Safety and Health ("NIOSH") of

the Centers for Disease Control and Prevention. The NTP is responsible for preparing the Report on Carcinogens (“RoC”), a document that lists substances “either known or reasonably anticipated to be human carcinogens.” The RoC is published every two years after the NTP’s review process.

38. Dr. Susan Nicholson (“Nicholson”) has been an employee at J&J since 2006. From March 2015 to May 2018, she was VP of Safety Surveillance and Risk Management at the Office of Consumer Medical Safety at J&J. During that time, she spent months reviewing the safety of talc, including reviewing hundreds of papers on talc and ovarian cancer.

39. Lorena Telofski (“Telofski”) is a long-time employee of J&J, beginning in 1979. As of 2017, Telofski was Associate Director of R&D at JJCI, with a focus on Johnson’s Baby products.

40. Dr. Joanne Waldstreicher (“Waldstreicher”) is Chief Medical Officer (“CMO”) at J&J. She became CMO in the period of late 2012/early 2013. Waldstreicher met with Nicholson in November 2015 to do a review of the issues surrounding talc, including potential asbestos contamination.

41. Windsor Minerals was J&J’s subsidiary mining operation in Windsor, Vermont until it was sold in 1989 to Cyprus Minerals (“Cypress”).

V. COMPREHENSIVE STATEMENT OF THE CASE

A. Background

42. Johnson & Johnson is a healthcare conglomerate with three core businesses: Pharmaceutical, Medical Devices, and Consumer. Incorporated in 1887, J&J has grown exponentially over the years and considers itself to be “the world’s largest and most broadly based healthcare company.” Publicly, J&J has credited its longevity and success to the Company’s “Credo.” First written over 75 years ago, shortly before J&J became a publicly traded company, “Our Credo” delineates J&J’s responsibilities to medical professionals, patients, and parents, as well as to its employees, communities, and shareholders. Engraved in an eight-foot sandstone slab weighing some 30,000 pounds that is proudly displayed in the lobby of J&J’s corporate headquarters, “Our Credo” is “ubiquitous” within J&J offices, appearing on desktops, bookshelves, walls, and hallways. It states in part that J&J’s “first responsibility is to the doctors, nurses and patients, to mothers and fathers and all others who use our products and services. In meeting their needs everything we do must be of high quality.”

43. Along with the Company’s “Credo,” Johnson’s Baby Powder stands out as a symbol of J&J’s history and legacy. Recognized by J&J as a ““flagship product”” and ““sacred cow”” amongst the Company’s other offerings, Johnson’s Baby Powder is easily among “the top one or two products that people think of when they think of

J&J.” Not only does each bottle prominently display the Company’s name, but according to J&J’s own internal documents, the fragrance of Johnson’s Baby Powder is “the most widely recognized fragrance in the United States.”³

44. The storied past of Johnson’s Baby Powder helps to further explain why J&J has considered the product to be its ““sacred cow.””⁴ “[T]he Company’s baby products business was born” when Johnson’s Baby Powder “made its debut in 1893, [and] went on the market in 1894.” A 2007 J&J blog post explains:

Johnson’s Baby Powder was a success, and the Company began expanding its line of baby products to include creams, soaps, and more. Over time, Johnson’s Baby Powder, with its instantly recognizable scent, became *one of the most familiar and trusted products in the world*.

45. After World War I, J&J conducted “the largest ad campaign in its history” in order to promote the Company’s Baby Powder, which then became “trusted” by parents and associated “with the parent-infant bond”:

³ In an August 15, 2017 deposition, J&J corporate representative Hopkins admitted that Johnson’s Baby Powder was a flagship product and that “the baby powder is easily the top one or two products that people think of when they think of J&J.” He also admitted that “[i]n so far as Johnson’s Baby Powder was a sacred cow, an institution, a franchise, a flagship, a cornerstone of Johnson & Johnson’s business, it would be very, very bad for business if it ever came out that the baby powder or any of Johnson & Johnson’s talc products ever contained asbestos.”

⁴ Merriam-Webster defines “sacred cow” as “one that is often unreasonably immune from criticism or opposition.” Similarly, Dictionary.com defines “sacred cow” as “an individual, organization, institution, etc., considered to be exempt from criticism or questioning.”

With the rapid growth of advertising in the Nineteen-teens after World War I, Johnson & Johnson advertised Baby Powder with the largest ad campaign in its history, with the result that the powder – and the Company’s other baby products – really took off and ***became trusted components of the way families across the world cared for their children***. The products, by their very use, promoted close interaction between parents and their babies, and ***became associated in people’s minds with the parent-infant bond***.

46. As a result, J&J has long been known as “the Baby Company,” even as it has acquired other brands and products:

Generations of families have used these products to care for their children, and consumer identification with them has been so strong that, ***despite the depth and breadth of its product lines, the Company has enjoyed a longstanding reputation as “the Baby Company.”***

And as an internal memorandum from 1966 emphasized, “Baby Powder represents ***the cornerstone of [the Company’s] baby products franchise.***”

47. J&J has worked hard over the years to preserve the wholesome image of its flagship product. At least as far back as the 1970s, the Company told doctors and nurses how J&J’s Baby Powder was an “institution,” passed down in daily rituals from parent to child:

JOHNSON’S Baby Powder is an institution. For many years it has been a familiar sight in millions of homes, used by millions of parents in caring for young children. Its sweet-smelling fragrance has become ***associated with freshness, comfort, and cleanliness***.

48. Exploiting these memories and associations, J&J has historically urged people of all ages to “[t]hink of us as a lifetime friend of the family” and to continue to use Johnson’s baby products after childhood – promising that “[a]ll those good

comfortable feelings you felt when you were young stay with you as an adult.” Even today, J&J regularly reminds the public of the legacy and supposed benefits of Johnson’s Baby Powder. For example, on a 2016 webpage entitled “The Facts on talcum powder safety,” J&J boasted:

If you’ve ever cared for a baby, you’ve probably had JOHNSON’S Baby Powder in your home. Baby powder made from cosmetic talc is one of the JOHNSON’S brand’s oldest products and ***a longtime part of baby care rituals.*** It is hypoallergenic, helps eliminate friction and is clinically proven to be gentle and mild for your baby’s skin. ***The clean, classic scent is comforting and familiar for parents and children alike.***

49. Despite all of the Company-promoted associations with sentimental rituals and memories, Johnson’s Baby Powder is essentially just ground up minerals with a bit of “fragrance.” The principle ingredient of the Company’s Baby Powder and talcum powder products is talc, a naturally occurring mineral that is first mined and then ground into powder form.⁵

50. Talc can be naturally contaminated with asbestos, as the two can develop together within the same ore bodies. Asbestos is the commercial term used to

⁵ Johnson & Johnson has sold two principal talcum powder products over the years: Johnson’s Baby Powder and Shower to Shower. Valeant Pharmaceuticals International Inc. bought Shower to Shower from J&J in 2012.

From the mid-1960s until 1989, J&J’s talc was largely supplied by its own subsidiary, Windsor Minerals, and came from its Vermont mining operation. As a 1966 J&J memorandum illustrates, J&J historically had “a large investment in a talc mine.” Currently, Johnson’s Baby Powder sold in the U.S. contains talc that is imported from mines in China and supplied by Imerys.

describe minerals developing naturally as bundles of long, thin fibers that are flexible and easily separable, rather than as solid rock. These “asbestiform” minerals include chrysotile, tremolite asbestos, actinolite asbestos, anthophyllite asbestos, amosite, and crocidolite. Asbestos fibers can cause fatal cancers and wreak absolute havoc on human tissue, even when present in such small quantities that they are invisible without sophisticated detection methods and equipment. The U.S. federal government has made clear that *there is no known safe level of exposure to asbestos*. Even trace amounts are considered dangerous.⁶

B. The Early Years – Amidst Health Concerns Regarding Asbestos and Talc, J&J Begins Its Decades-Long Scheme to Conceal the Truth

51. Concerns about asbestos and its potential effects on human health grew during the 1960s, and as a result of this heightened awareness, questions about the safety of talc-based products and their potential asbestos contamination began to be raised in earnest in the early 1970s. Despite being repeatedly informed of the presence of asbestos in the Company’s talc and talcum powder, J&J lied to the public,

⁶ Tremolite, actinolite, and anthophyllite minerals can also develop naturally as larger rocks, *i.e.*, “non-asbestiform.” Importantly, however, these rock formations can be broken down by industrial processes such as grinding, leading to “cleavage fragments.” These fragments can have substantially similar characteristics as naturally occurring asbestos, with the potential to pose the same health risks as “asbestiform” minerals. In addition, according to Richard Zazenski (“Zazenski”), long-time employee of J&J’s talc supplier, “if a deposit contains ‘non-asbestiform’ tremolite, there is also asbestiform tremolite naturally present as well.” In other words, where there is tremolite there is asbestos present.

influenced regulators, and purposely avoided testing methods that could detect the trace amounts of asbestos that the Company knew were present.

1. J&J Recognizes Internally that Its Talc Is Contaminated and that It Could Lead to a Public “Furor” and Litigation

52. By 1969, J&J had already recognized that asbestos contamination posed a direct threat to the Company’s iconic brand and raised the specter of litigation exposure. In a 1969 memorandum, Dr. T.M. Thompson (“Thompson”) of J&J noted the general concerns that had previously been raised about the safety of Johnson’s Baby Powder, including by Robert Wood “General” Johnson II (“General Johnson”), son of J&J co-founder Robert Wood Johnson.⁷ Thompson indicated that General Johnson and numerous pediatricians had “express[ed] concern” about potential “adverse effects on the lungs of babies or mothers.” Thompson then went on to admit that J&J’s talc contained “unavoidable trace amounts” of tremolite, and that these structures could penetrate deep inside the lungs:

[W]e have occasionally received inquiries from various individuals, including General Johnson and several pediatricians, *expressing concern over the possibility of the adverse effects on the lungs of babies or mothers* who might inhale any substantial amounts of our talc formulations. In the past, we have replied to the effect that since our talc is essentially all of the platelet-type of crystalline structure, and is of a size which would not be likely to *enter the pulmonary alveoli*, we would

⁷ General Johnson, who served as chairman of the Company from 1932-1963, has been credited with turning J&J into the largest health-care company in the world. He also wrote J&J’s celebrated Credo.

not regard the usage of our powders as presenting any hazard. Obviously, if we do include Tremolite in more than *unavoidable trace amounts*, this sort of negation of such inquiries could no longer pertain.

53. Thompson also acknowledged to other Company personnel, including Ashton, that “if it became known that [its] talc formulations contained any significant amount of Tremolite,” J&J could face “such a furor” that it could be “more or less compelled to remove [tremolite] from the formulation”:

Some years ago, we were faced with a more or less serious problem resulting from what we consider to have been an unjust accusation of danger due to the presence of a small amount of boric acid in our talc. This *created such a furor* that we were more or less compelled to remove boric acid from the formulation. It is conceivable that *a similar situation might eventually arise if it became known that our talc formulations contained any significant amount of Tremolite*.

Thompson further warned that the Company could face litigation over tremolite in its talc, and he suggested that the Company’s law department be involved:

Since the usage of these products is so widespread, and the existence of pulmonary disease is increasing, it is not inconceivable that *we could become involved in litigation* in which pulmonary fibrosis or other changes might be rightfully or wrongfully attributed to inhalation of our powder formulations. It might be that *someone in the Law Department should be consulted with regard to the defensibility of our position* in the event that such a situation could ever arise.

2. J&J Tells the Public that the Company’s Baby Powder Contains No Asbestos, but Numerous Internal Documents and J&J’s Own Efforts to Remove the Asbestos Show Otherwise

54. In June 1971, J&J attempted to put concerns about its talc to rest by issuing a statement to the *New York Daily News* and *New York Post*:

Johnson & Johnson takes great care to assure the purity of its products, even to the extent of mining and processing our own talc for use in baby powder. Our fifty years of research knowledge in this area indicates that *there is no asbestos contained in the powder manufactured by Johnson & Johnson.*

55. Contrary to J&J's public assurance, however, the Company already knew that its talc contained asbestos. Indeed, a little over a month after J&J's June 1971 press release assuring based on "fifty years of research knowledge" that the powder contained "no asbestos," a July 1971 memorandum by J&J's Wilson Nashed noted that "[t]he talc used in JOHNSON'S Baby Powder" came from a Vermont mine containing "trace amounts of fibrous minerals (tremolite/actinolite)." While the talc went through a "washing process," "three independent consulting laboratories" showed that the resulting talc still had "traces of fibrous minerals":

The talc used in JOHNSON'S Baby Powder is obtained from a selected mine in Vermont where the ore consists mainly of platy talc with only *trace amounts of fibrous minerals (tremolite/actinolite)*. It is free of chrysotile fibers which may be called "pure asbestos" by the layman.

The ore undergoes a careful purifying process which includes a 36-step washing process to maximize its content of high lubricity platy talc and to remove or substantially reduce any traces of fibrous minerals which may be present in the unrefined ore. *The resulting talc has been shown by three independent consulting laboratories[] to contain negligible traces of fibrous minerals* and no chrysotile fibers.

56. Then, in 1972, University of Minnesota professor Thomas E. Hutchinson ("Professor Hutchinson") tested talcum powder samples received from J&J and an outside laboratory, and he found chrysotile in a Shower to Shower sample – or what

he described as “*incontrovertible asbestos*” in a lab note. While J&J submitted testing results to the FDA and claimed that they “clearly show[ed]” “no chrysotile asbestos,” J&J withheld the findings of Professor Hutchinson.

57. In August 1972, J&J was informed by Dr. Weissler, Director of the Division of Cosmetics at the FDA, that a sample of J&J’s Shower to Shower talcum powder product had been sent to Sperry Rand, an outside laboratory facility, and that the report “was that *asbestos fibers could be detected*.” J&J attempted to discredit the results, asking Dr. Weissler about the facility’s experience and potential for lab contamination, but internally *admitted the potential presence of tremolite fibers in its products*:

The report from Sperry Rand was that *asbestos fibers could be detected* in the sample. Dr. Weissler said that he has in front of him photographs of 6 fields at 12,000X magnification showing fibers with length to width ratios of 10-to-1 to 50-to-1

I asked Dr. Weissler if the Sperry Rand facility handles minerals. He said yes, they do a lot of work with chrysotile. I asked him, “Have they reported to you the normal background contamination in their samples. As you recall, this was the problem in Mt. Sinai’s laboratories.” He said no; however, he feels that the man who did the work is conservative and would not have reported chrysotile unless he was sure. *I asked him if he has assured himself that the fibers were not tremolite which could be present in trace amounts. He said the fibers are characteristic of chrysotile* and not tremolite.

58. Other internal documents from the 1970s also demonstrate J&J’s awareness of its asbestos contamination problem. For example, a February 1973 Company memorandum illustrates that J&J consultant Fred Pooley was working on a

process to remove tremolite from talc, which Tom Shelley (“Shelley”), Director of J&J’s Central Research Laboratories, considered to be potentially a “valuable patent” for J&J. But after a little over a month of contemplation, Shelley determined that it could be in J&J’s best interest to “*keep the whole thing confidential*” rather than “*let the whole world know*” that J&J was trying to remove asbestos from its talc:

[W]e will want to carefully consider the Pooley patents re asbestos in talc. It’s quite possible that we may wish to keep the whole thing confidential rather than allow it to be published in patent form and thus let the whole world know.

59. Then, in August 1973, J&J was informed that the Dutch Consumer Organization had found asbestos in Johnson’s Baby Powder. J&J asked the organization to not make its findings public. A December 13, 1973 letter from J&J’s operation in the Netherlands, with “*asbestos in baby powder*” as the subject, stated:

During the month August the Dutch Consumer Organization has informed us that *they have determined asbestos in JOHNSON’s Baby Powder*.

According to their first test the content was 1.59%.

On our request they have tested another sample and the result of this second test was 0.3%.

During the period August/November we have had continuous contacts with them and we have supplied them with all the data and comments we received from Johnson & Johnson U.S.A. and Johnson & Johnson U.K.

We also asked them clearly not to make any publications about asbestos in baby powder, before we agreed with their findings.

Because *they did not accept our arguments against their method of testing* we have proposed a discussion between our experts and theirs.

We have tried this several times.

60. By 1974, J&J was also authorizing asbestos-destruction experiments in Colorado. An April 1974 memorandum containing notes on a visit with the Colorado School of Mines details J&J's authorization of experiments to establish the destruction of tremolite and chrysotile in the presence of Vermont talc, and to "[d]etermine whether or not fibrous structure is retained or destroyed in above." Once again, J&J was considering turning a profit on the asbestos contamination, as the experiments were "to be *run on [the] low key,*" "*up to [the] point where we can file patent protection.*"

3. J&J Sets out to Influence Regulators and Purposely Avoids "Essential" Asbestos Testing Methods

61. Knowing that there were "unavoidable trace amounts" of tremolite (asbestos) in its talc, J&J also knew that it would likely fail in finding a way to completely eliminate asbestos from its talc. This made it even more critical that J&J prevent the asbestos contamination from becoming public knowledge. The Company embarked on a campaign to undermine scrutiny by public health officials and doctors, branded internally in November 1972 as "*Antagonistic Personalities.*" These individuals included the Director of the Environmental Protection Agency ("EPA") of New York City, an FDA official "who [was] seeking recognition within the FDA" and "seem[ed] particularly anxious to condemn talc," and a doctor at the Mt. Sinai

Hospital and others in his department with “the same mental attitude,” including Dr. Arthur Langer (“Langer”), *who had told J&J of his finding of asbestos in J&J’s “baby talc” the year prior* in a November 1971 letter.⁸

62. In defending its flagship product, J&J paid particular attention to the FDA and directly sought to influence it. For example, in October 1973, J&J analyzed a proposed FDA regulation regarding the method for determining the presence of asbestos in food and drugs, determining that while the method of analysis would “show that our talc is acceptable,” *“if they change the method, we may have problems.”* J&J then contributed to a December 1973 letter from the CTFA to the FDA arguing that it was “premature for FDA to impose its proposed optical method and place a limit on asbestos in talc for food use.”

63. Meanwhile, J&J purposely avoided essential testing methods. As J&J’s own consultant, Colorado School of Mines, confirmed in December 1973, looking for trace amounts of asbestos in talc is like trying to find a “needle in a haystack,” and so requires looking at an increasing amount of talc. In order to do this, a method of preconcentrating any asbestos content is “essential”:

As the impurity level becomes very low ($\ll 1\%$), it is necessary to examine increasingly larger amounts of sample in order to detect the impurity. As a result of the requirement to detect the proverbial “*needle*

⁸ *Reuters* would report in December 2018 that “Langer said he told J&J lawyers who visited him last year that he stood by all of his findings,” which included “trace amounts of chrysotile asbestos” in J&J’s talc.

in a haystack,” we have evolved a procedure which preconcentrates the impurities prior to examination.

* * *

The objective of this work was to develop a procedure to screen talc for the presence of chrysotile and tremolite-actinolite asbestos minerals. Based on past experiences with detecting and identifying minerals when present at low levels, ***a concentration of the phases to be detected was considered essential*** to the success of any suggested procedure. Once concentrated the impurities could be detected by conventional methods of examination.

64. A May 1973 J&J report entitled “Proposed Specs for Analyzing Talc for Asbestos” illustrates that J&J knew that asbestos was in the Company’s talc and that concentration methods would allow laboratories to find it, making such methods “too sensitive” for J&J’s taste:

England is considering method of preconcentrating the asbestos so as to be able to analyze by X-ray. They find no “asbestos” by doing this with Italian talc. ***They find (Pooley) 0.05% of a tremolite-type in Vermont.***

* * *

Preconcentration of Asbestos followed by X-Ray Diffraction Analysis (Pooley Method)

Dr. Pooley has developed two techniques for preconcentration of chrysotile and tremolite in talc followed by X-ray diffraction analysis. . . . The second technique developed also by Dr. Pooley involves preconcentration of tremolite in talc (different procedure) followed by X-ray diffraction analysis. This technique has not been written up yet, but evidently ***when applied to Vermont talc, 0.05% of tremolite-type is found. The limitation of this method is that it may be too sensitive.***

65. J&J's purposeful avoidance of sophisticated testing methods is further evidenced in a February 1975 internal J&J memo to the Company's British operation, attaching "minutes of the CTFA task force on methodology for the detection of asbestos in talc" and stating that J&J was looking at these methods "very quietly" "to avoid promotion of this approach":

We are presently practicing and evaluating the Pooley flotation method so we are not in the position to recommend it at this time. Besides, *we feel that a detectability limit with our two present methods of 0.5% to 1% is reasonable* Our major problem with the Pooley procedure is that since one can continually recycle the tailings (concentrate) given enough time, it is possible to arrive at levels of detectability of asbestos in talc in the ppm range – at what stage of recycling do you stop? *We really want to exclude concentration techniques in any proposed analytical procedure and are really looking at this method very quietly* so that we will be informed and up-to-date with this area of technology. *We want to avoid promotion of this approach.*

66. A November 1976 J&J memorandum from Ashton declared that separation and concentration techniques were "disturbing," as their implementation would make the talc industry "hard pressed in supporting purity claims" and could "open up new problem areas with asbestos and talc minerals":

Attached is a copy of *a disturbing proposal request* which the FDA has currently made available to qualified bidders. The scope of the work is the Separation of Asbestos in Foods, Drugs and Talc for Identification and Determination.

I find this proposal more disturbing than other proposals up to now because it aims at separation and isolation of asbestos from a wide scope of products and animal tissues. Up to now, our main problems have had to do with identification, whereas, now it looks like *the FDA is*

getting into separation and isolation methodology which will mean concentration procedures. As I have pointed out many times, there are many talcs on all markets which will be hard pressed in supporting purity claims, when ultra sophisticated assay separation and isolation techniques are applied. Chances are that this FDA proposal will open up new problem areas with asbestos and talc minerals.

67. To this day, J&J has not adopted a concentration method for testing its talc despite the Company's knowledge that this would allow detection of asbestos in its talc and talcum powders when present in trace amounts.

4. J&J Monitors and Defends Against Science and Regulations

68. During the 1970s, while J&J worked to avoid the use of sophisticated and "essential" testing methods on its products, the Company also set out to defend its Baby Powder's image by undermining scientific studies and research. An internal memorandum from March 1975 ("March 1975 memorandum") illustrates that J&J's initial approach "with respect to *sponsorship of talc safety studies*" had been defensive, with J&J "initiat[ing] studies only as dictated by confrontation." The March 1975 memorandum recognized that this approach "has allowed us to *neutralize or hold in check data already generated* by investigators who question the safety of talc." Much like an ostrich with its head in the sand, J&J's "principal advantage" with this approach was that it "minimize[d] the risk" of J&J itself inadvertently generating "scientific data which may be politically or scientifically embarrassing." Activities proposed under this approach included (i) involvement in a study "directed towards

demonstrating that pulmonary function is not impaired by exposure to cosmetic grade talc,” and (ii) funding “Johnson & Johnson’s monitoring of the NIOSH Harvard Study of Vermont Talc Workers” and J&J’s “analytical and statistical verification of the data to be gathered.”

69. But the March 1975 memorandum also acknowledged the weaknesses of this defensive strategy:

[T]his approach leaves the talc franchise and the company image open to repeated erosion by prior public disclosure of suspected hazards and adversary politicking. Also, there exists a danger that the latent period for generating J&J data might be too great for the data to be effective.

70. Thus, the March 1975 memorandum proposed “a more anticipative approach” that had been discussed at the Talc Advisory Group:

We would *carry out other reasonable safety studies to continue our contradiction of generated negative data* and to anticipate questions on safety which will probably be raised. This philosophy offers *maximal leverage for defending the product*

71. An August 1977 J&J “Status Report” on the “Defense of Talc Safety” provided an update on “*the talc safety defense program*” that J&J had been conducting. Noting that cosmetic talcs had not suffered “disruptive influences” in the past two months, J&J recognized the effectiveness of “the various J&J sponsored studies [that had] been disseminated effectively” to the United Kingdom and U.S. scientific and medical communities:

The past two months have seen no disruptive influences and to the contrary, the *cosmetic talcs have enjoyed confirming reassurance* from

several independent authoritative sources that they are assessed to be free of hazard for normal consumer use.

We attribute this growing opinion to the fact that (1) the existence of CTFA's self-regulating cosmetic grade talc specification has become common knowledge and that (2) favorable data from ***the various J & J sponsored studies have been disseminated effectively to the scientific and medical communities*** in the U.K. and U.S.

72. An internal J&J report regarding the Company's "Special Talc Study," for the period of December 1977 – January 1978, illustrates J&J's continued efforts of creating research and data that could be used to protect "the safety image" of Johnson's Baby Powder:

OBJECTIVE:

To monitor and defend against consumerist, scientific and regulatory attitudes/trends which could impact adversely on the safety image and marketability of cosmetic talcs.

To generate or provide necessary data to support and reinforce the safety of our baby powder.

73. The "Special Talc Study" report also explains how ***J&J was again informed that its Baby Powder and talc were contaminated with asbestos.*** "A visit was made" to a facility to preview "a new instrument" that "detects and counts airborne fibers in the presence of high concentrations of non-fibrous particles." Johnson's Baby Powder and J&J's talc were tested with this device, and the "results indicat[ed] our talc and product are well below the current 2 fibers/cc permitted for asbestos," as "JBP" (Johnson's Baby Powder) had come back with 0.08 fibers/cc and J&J's V-66 Talc had come back with 0.28 fibers/cc.

C. 1980s to 2000s – J&J Faces a New Battlefront in the War to Defend Its Flagship Product: the Association Between the Use of Talcum Powder and Ovarian Cancer

74. Beginning in the 1980s, J&J faced a growing body of research finding evidence of an association between talcum powder usage for personal hygiene and ovarian cancer. Notably, because J&J had convinced the world that the Company's talcum powders were asbestos-free, the public health research focused on the question of whether there was a connection between ovarian cancer and the talc itself.

75. Knowing that public health researchers were bringing increased attention to talc and that this could threaten J&J's concealment of its talc's asbestos contamination, J&J sold its Hammondsville mine, which had served as *the primary source of talc for J&J's flagship product since 1966*, to Cyprus in 1989. J&J did this shortly after *destroying most of the records* of the Hammondsville mining operation.

A November 23, 1993 J&J memorandum explains:

The specifics of the mining operation at Hammondsville are uncertain, as most of the pre-Luzenac records were destroyed by the mine management staff just prior to the J&J divestiture and the Cyprus purchase. However, several former Hammondsville miners are still employed at the Ham mine, and they provided us with useful information as to the nature of the underground works.

76. Meanwhile, a March 1992 internal memorandum at J&J's talc supplier illustrates that it was common knowledge at the Vermont mining operation that asbestiform minerals were present. Indeed, the memorandum illustrates that there was

“certainly visible tremolite and actinolite in specific zones,” and that “Cyprus staff report past tremolite from the Hammondsville and Clifton deposits”:

Vermont talcs are derived from altered serpentine – *a natural host for asbestiform minerals*. *There is certainly visible tremolite and actinolite in specific zones of the Vermont deposits* – fibrous tremolite was identified by the writer in exposures and cores at the East Argonaut and Black Bear mines. *Cyprus staff report past tremolite from the Hammondsville and Clifton deposits*.

77. As researchers examined talc as a potential carcinogen, government interest in talc returned and NIOSH nominated talc for study by the NTP. In 1993, the NTP reported finding evidence of talc’s “carcinogenic activity” in an inhalation study performed with rodents. With public health researchers and regulators moving closer to discovering J&J’s massive cover-up, the Company took aggressive action to conceal the asbestos contamination of its talc and talcum powders.

1. Through Falsehoods and Manipulation, J&J and Its Industry Cohorts Successfully Prevent Talc from Being Listed in the “10th Report on Carcinogens”

78. As government interest in talc grew, J&J set out to stay “at the forefront of cosmetic talc” and have “worldwide oversight on talc issues.” An August 1993 internal memorandum from Donald Jones to John Hopkins stated:

John, I’m sure you’ve heard that FDA asked ISRTP to organize a talc safety symposium. The request is a follow-up to both the 1992 NTP findings regarding talc and the 1992 Harlow paper resurfacing the ovarian cancer connection to cosmetic talc use first proposed by Cramer.

* * *

[A]s part of a strategy to *keep J&J at the forefront of cosmetic talc*, and to *insure that we have worldwide oversight on talc issues*, Mary Ann Cook and I are organizing a Worldwide Talc Steering Committee.

79. At the same time, J&J also continued to receive dire warnings regarding its talcum powder's association with ovarian cancer. For example, in a November 10, 1994 letter from the Cancer Prevention Coalition, J&J's CEO at the time, Ralph Larson, was alerted to the scientific evidence of an association between talcum powder and ovarian cancer:

Dear Mr. Larson,

A wide range of scientific studies dating back to the 1960s shows conclusively that the frequent use of talcum powder in the genital area poses a serious risk of ovarian cancer.

Dr. Bernard Harlow, a leading ovarian cancer researcher from Harvard Medical School, published a comprehensive study in 1992 of the link between talc and ovarian cancer. The study found a threefold increase of ovarian cancer in women who used talc in the genital area as a daily habit.

* * *

Furthermore, the U.S. National Toxicology Program has recently confirmed that talc is carcinogenic.

80. By September 1997, J&J was participating in industry representations that J&J's own consultant described as "inept," "inaccurate," and "outright false," all in an effort to conceal the asbestos contamination of its flagship product. In a letter from Alfred Wehner ("Wehner") to J&J's Manager of Preclinical Toxicology Michael

Chudkowski (“Chudkowski”), J&J was warned of the troubling posture it was taking along with its industry allies:

Several investigators have independently reported talc particles in ovarian tissue. Simply citing the Battelle study and stating that it “demonstrated that talc does not translate (sic!) through the cervix to the uterine cavity and beyond does not address the problem All in all, in my opinion an inept response.

The problem with the response statement dated July 8, 1992, is more serious. The last sentence in the second paragraph states: “Finally, human studies on talc and cancer in industrial settings have shown that industrial exposure to talc, both by skin contact and inhalation, even at levels thousands of times higher than lifetime consumer exposure, presents no significant risk.” *This statement is outright false.*

* * *

The response statement dated November 17, 1994, is just as bad. The second sentence in the third paragraph reads: “The workshop concluded that, although some of these studies suggest a weak association might exist, when taken together the results of the studies are insufficient to demonstrate any real association.” This statement is also inaccurate, to phrase it euphemistically. At that time there had been about 9 studies (more by now) published in the open literature that did show a statistically significant association between hygienic talc use and ovarian cancer. *Anybody who denies this risks that the talc industry will be perceived by the public like it perceives the cigarette industry: denying the obvious in the face of all evidence to the contrary.*

81. At the same time that J&J and its allies were vehemently denying the link between talc and ovarian cancer in order to avoid the public discovery of the asbestos contamination, J&J was again informed that its talcum powder was contaminated with asbestos. In an April 1998 letter to Mehaffy & Weber, lawyers for JJCI, Dr. Alice Blount (“Blount”) stated that J&J’s talc “contains trace amounts of asbestos”:

Although my papers report an improved method for analysis, the determinations for the sample labeled *I* (Johnson & Johnson's Vermont talc) have been done by the traditional methods as well ***As I told you, I believe that Johnson & Johnson's Vermont talc contains trace amounts of asbestos*** which are well below those specified by OSHA.

Blount identified J&J's Vermont talc as the Sample I from her 1991 paper, which detailed her findings of asbestos "[n]eedles and fibers" in that sample and that the aspect ratio distribution for Sample I tracked that of tremolite asbestos.

82. By October 2000, the first two groups of the NTP's review process had voted 13-2 in favor of listing talc in the 10th RoC. This raised the stakes considerably for J&J, bringing researchers and regulators one step closer to discovering J&J's longstanding fraud. In response, J&J and its talc supplier worked to undermine the NTP, and by November 27, 2000, J&J's talc supplier had found and proudly shared with J&J the "Winning Hand" in how to defeat the NTP. In an email to J&J's Chudkowski attaching comments from lobbying group CRE, Luzenac's Zazenski boasted that the companies now had a way to get talc out of "this NTP nonsense":

I'll let you guys read this for now . . . but it's for your eye's only until we finalize it. It's the winning hand in getting talc without asbestos dismissed from this NTP nonsense.

For now, I'll graciously accept 100% of the credit 1) finding CRE, 2) convincing them to get involved, 3) developing ***the Fatal-Flaw Strategy***[,] 4) single-handedly ***saving the talc business from certain ruin***.

All in a day's work. All contributions to the RJZ vacation and retirement fund will be accepted.

83. As it turns out, the “fatal flaw” was rather simple. Because many of the epidemiology studies linking genital talc use to ovarian cancer did not distinguish talcum powders produced after 1976 (which was purportedly required to be “asbestos-free”) from those produced before 1976, it was supposedly impossible to know whether the results were because of asbestos in the talc or because of the talc itself. As Zazenski would explain:

*The primary reason non-asbestiform talc was able to survive the third NTP meeting in December and not be recommended for listing **was the introduction of doubt** concerning the characterization of talc utilized in dusting powders cited in the epidemiology studies. All but one of the sixteen ovarian cancer studies would have involved the use of cosmetic talc and baby powder produced prior to 1976, the year that CTFA introduced cosmetic talc specifications requiring no asbestos.*

Two days after the draft CRE comments were shared with J&J, the CRE submitted its letter to the NTP, claiming that CRE “is not affiliated with any particular industry, company, or other entity.”

84. The “fatal flaw” strategy was successful, as the NTP deferred consideration of listing talc because “there ha[d] been considerable confusion over the mineral nature and consequences of exposure to talc, both containing asbestiform fibers and not containing asbestiform fibers.” In response to an e-mail from Mann referencing Zazenski’s “history with J&J on defending talc,” Zazenski would provide further details:

[D]uring the 10th RoC review, the Center for Regulatory Effectiveness (Washington, D.C.) took an active role in ensuring that NTP was

conducting a proper review of talc. *CRE was instrumental in helping divert an almost guaranteed listing for talc into a “deferral. . . .”* I might point out that in the 10th RoC review, RG1 and RG2 voted 13-2 to list talc (not containing asbestos) as a carcinogen. Up until then, every substance nominated for listing by both RG1 and RG2 went on to be listed.

85. As J&J’s talc supplier also summarized the events internally, admitting that, “[w]e (*the talc industry*) *dodged a bullet . . . based entirely on the confusion over the definition issue.*” Of course, the cruel irony that J&J and Luzenac failed to mention to the NTP or the public health researchers was that the “fatal flaw” was illusory, as J&J’s talc and Baby Powder continued to be contaminated with asbestos.

86. But while J&J was able to keep talc off of the NTP’s 10th RoC, fears of its fraudulent scheme being revealed lingered at the Company as it faced the threat of the NTP post-deferral, as well as a new potential foe – the WHO’s International Agency for Research on Cancer, or IARC, which “[u]nlike NTP,” was “answerable to no one politically.” As Zazenski warned Ashton on March 26, 2002:

We’ve been successful thus far in fending off the NTP classification of talc as being a potential human carcinogen. But we must also *keep an eye out for IARC. . . .* IARC reviews are not a public debate. Unlike NTP, *IARC is answerable to no one politically* (they are headquartered in Lyon, France of all places). As part of the World Health Organization, *they act very independently to protect the citizens of this planet* from ‘preventable’ diseases. . . . You might want to counsel your management on this potential (and *not to be too complacent about the status of talc*).

2. J&J Recognizes Internally that the “Fatal Flaw” Is an Illusion and Is yet Again Put on Notice that Its Baby Powder Is Contaminated with Asbestos

87. J&J’s knowledge regarding its talc’s asbestos contamination is illustrated by a February 2002 email between Mann and Telofski about telling the NTP that there was “never” asbestos in J&J’s talc:

[Mann to Telofski]: I’d like to tell CTFA that we are OK with forwarding that lit. review to NTP. *Did you have a suggestion on a sentence that addresses the fact that our source of talc “never” had asbestos in it.*

* * *

[Telofski to Mann]: I did review the lit – no surprises there and okay to send. *I still don’t have a terrific suggestion regarding the asbestos* – let’s handle as we discussed and I will see if I can get a better idea going in meantime.

Soon after this internal struggle over the claim that Johnson’s Baby Powder “never” had asbestos in it, Mann and others at J&J were discussing the fragrance of Johnson’s Baby Powder and the sourcing of the Company’s talc. In a June 30, 2003 email with the subject “JB Powder w China Talc,” Mann gave his take on whether the fragrance would be changed: “[m]y sense is that the Baby Powder is such a ‘Scared Cow’ [sic] that we will just leave it alone.” Less than a year later, Mann and others at J&J learned that the ““sacred cow”” *still* had asbestos in it.

88. In 2004, as part of a special report about asbestos in the community, KCRA TV3 of Sacramento, California had Johnson’s Baby Powder tested for asbestos by outside testing company Forensic Analytical. Through that testing, the news

channel discovered that Johnson's Baby Powder "*tested at above normal levels for asbestos.*" A reporter for the television station informed J&J's Marc Monseau ("Monseau") of these results and enclosed a copy of the test results showing **0.20% Asbestos Weight Percent for Johnson's Baby Powder**. On February 24, 2004, with the subject "Re: Asbestos," Monseau faxed the information to Mann. Referring to "the attached cover letter and lab results" from the television station, Monseau also told Mann, "Sarah Colamarino suggested I share with you. Can you please review? Sarah will be calling you shortly to discuss."⁹

89. The same day that Mann found out that the news station had discovered asbestos in Johnson's Baby Powder, he received an email from Hopkins suggesting how to deal with the media, following up on a prior conversation they had. Hopkins suggested "that *it is important that you ensure compliance of the current talc with the CTFA Specification.*" According to the email from Hopkins:

A certificate as such from an independent source (RJ Lee) is an easier way of dealing with non-experts (*i.e.*, media) than talking about the various kinds of mineralogy of talc. You can then *enlist CTFA as a buffer to deal with these issues*. Feel free to call anytime. Also I know Bill Ashton would want to help and is OK to call at home. In fact he would expect to be involved if his mineral expertise could be of value.

⁹ Colamarino was VP of Communications at J&J's consumer division from 2000 to 2004. In that position, Colamarino worked on "global issues management and crisis communication, . . . brand public relations programs and initiatives closely integrated with Johnson & Johnson reputation-building strategies."

90. J&J took its former employee's advice to heart. In fact, according to a March 22, 2004 email from Julie Pier of Luzenac, J&J "frantically" called its talc supplier, "ask[ing] where all the data was on their product." As it turned out, J&J's talc supplier had failed *for three years* to do quarterly testing, without J&J ever noticing:

Johnson & Johnson called us frantically, because some outside lab apparently found asbestos in off-the-shelf baby powder. *Some expose' will be coming out*, supposedly . . . *it prompted J&J to ask us where all the data was on their product*. I was supposed to be doing quarterly samples by TEM, but *they were all in the backlog*. *Since 2001. Oops . . .* I had to scramble and try to catch up. I worked like crazy and it was the source of a 'HIPO' (high potential for loss incident). . . . They are also frantically trying to find a 'clean area' in Penhorwood, so they submitted 60 samples for TEM!!! Physically impossible to do based on their time frame.

91. As part of J&J's "frantic" response to the KCRA TV3/Forensic Analytical report of asbestos in Johnson's Baby Powder, the Company also re-involved Ashton, as Hopkins had suggested. Ashton was technically retired from J&J at this time, but he continued to come into the J&J offices in New Jersey once a week or every two weeks. A letter from RJ Lee addressed to Ashton at J&J's consumer division in Skillman, New Jersey discusses the Forensic Analytical report:

The methodology used by Forensic Analytical is the standard EPA Test Method for the determination of Asbestos in bulk building material. There is no supporting evidence to show what was found. Before this information is released you should see the following documents:

(1) The count sheets that show the number and size of the structures that were seen.

(2) Photos that show if these structures are cleavage or asbestiform.

(3) EDS (Energy Dispersive Spectra) to show the elements present and their ratio.

(4) The SAED (Selected area Electron Diffraction) patterns to show the crystal system-similar to XRD.

If you need interpretation of their documents, we would be glad to work with you.

92. Meanwhile, J&J's talc supplier had found chrysotile asbestos fibers *in its own testing* of "Grade 96" talc in 2002 and 2003, which was destined for Johnson's Baby Powder sold in Canada. Indeed, Imerys had found a chrysotile asbestos fiber in each of four separate samples during that time period.

3. Under the Direction of Defendant Casalvieri, J&J Sets out to Keep Talc out of the 12th RoC

93. Rather than come clean about asbestos in its Baby Powder, J&J continued to undermine efforts by the NTP, "utiliz[ing] all [its] power to defend" its Baby Powder, as J&J knew that the flagship product was "a primary link to the positive J&J name in the public mind." *The same year that he was alerted to asbestos contamination of Johnson's Baby Powder*, Mann wrote an email to numerous individuals at J&J:

I want to raise the level of risk to J&J from the NTP talc issue from Moderate to High. . . . I have had some recent conversations with our supplier Luzenac and our internal Talc Task Force, as well as CTFA.

There is a significant chance that NTP could make an unfavorable ruling and *that would have a major ripple effect as J&J Baby Powder is a primary link to the positive J&J name in the public mind*. I think we may be at the point where *we need to call upon major corporate resources and utilize all our power to defend against this*. I can discuss details off-line.

94. A few months later, a February 17, 2005 J&J email indicated that defendant Casaltieri was directing the project “to defend talc,” with Mann handling the “day-to-day” activities:

[Corinna Hengsberger of J&J:] I know *we have a project active to defend talc*. I also saw some info [with] some news for the regulatory [sic] side, in the US. As talc is a significant business globally, I was wondering whether we need to put this on the agenda for broader discussion?

[Robert Predale of J&J:] Yes – I agree we need to have broader discussion on talc. As you may know the talc issue is being *led primarily from our Tox folks under the direction of Joan Casaltieri* – Mann is the day-to-day person leading the effort.

95. And a February 17, 2005 email from Mann to J&J’s Hengsberger, Gerd Ries, defendant Casaltieri, Predale, Kathleen Wille, and Gaetan Rouleau emphasized the Company’s efforts to make sure talc was kept off the 12th RoC and the Company’s asbestos secrets stayed deeply buried:

I have been working on several fronts to *assure a good outcome*, including both working with the CTFA Talc Interested Party Task Force, and independently with our major supplier Luzenac and their Washington, DC legal team.

The CTFA Task Force provided extensive comments and documents to the NTP in July 2004 While we are waiting for the NTP Background Document I am working with Luzenac and outside epidemiology experts to *develop documents that scientifically support*

the lack of a relationship of talc and ovarian cancer. These documents will be submitted to NTP and for publication in the scientific literature. We have been proactively providing NTP all the scientific data available in support of talc through several channels.

Through the CTFA and our supplier contacts *we are monitoring closely NTP activity* in this area.

96. In response, Gerd Ries of J&J told Casavieri, Mann, and others that the “critical question” that would determine J&J’s strategy was *not* whether Johnson’s Baby Powder contained a carcinogen, but whether J&J could “prevent this classification”:

The critical question that determines how we need to handle this case internally is *what the chances are that we can prevent this classification.* Can you offer a percentage of success?

4. J&J Secretly Funds a Meta-Study Concluding that Talc Is Safe and Attempts to Influence the World Health Organization

97. In order to “develop documents” supporting the safety of talc, and thereby protect J&J’s sacred cow from having its asbestos contamination revealed, the Company had set out to fund academic research and then conceal J&J’s involvement. *A year after receiving the news that an independent lab had found asbestos in Johnson’s Baby Powder*, Mann informed Crowell & Moring lawyer Ridge Hall (“Hall”) that J&J management would provide funds for “the Huncharek/Muscat narrative on ovarian cancer and talc.” The study, authored by Joshua Muscat

(“Muscat”) and Michael Huncharek (“Huncharek”), was for possible submission to the NTP.¹⁰

98. To make the study happen, J&J and Luzenac both paid for it, splitting the cost. However, the researchers were only retained by Crowell & Moring, concealing J&J’s support of the study. A February 1, 2005 email from the law firm to Mann makes clear that this was by design:

As I mentioned during our discussion this morning, our plan is for Crowell & Moring to retain Drs. Huncharek and Muscat so as to preserve the benefit of the attorney work product privilege, which is helpful in protecting confidentiality.

99. Even payment to the researchers was funneled through the law firm, concealing J&J’s contribution entirely. As Hall explained the purpose of this plan in a February 28, 2005 email to Mann and others:

To maximize the effectiveness of our use of the attorney work product privilege for their work, I will plan to send them a Crowell & Moring check in that amount, to be reimbursed to us by Luzenac and Johnson & Johnson in whatever proportions you agree on.

100. By June 2005, the Company learned that the NTP had decided to let IARC take on the talc issue instead. In a June 28, 2005 email to at least 15 other individuals at J&J including defendant Casavieri, Mann warned that IARC was

¹⁰ Titled “Perineal Talc Use and Ovarian Cancer: A Critical Review,” the study was eventually published in the European Journal of Cancer Prevention in 2008. It concluded that the data taken collectively “do not indicate that cosmetic talc causes ovarian cancer.” It contains no reference to J&J’s funding of the study.

difficult to manipulate, but he also stated that CTFA and J&J were doing all they could to influence the IARC decision by seeking to get their own experts embedded in the IARC process, including John Hopkins, Muscat, and Huncharek:

It is VERY difficult to have any impact on the IARC, and this has recently been made even more difficult by rule changes that make industry input difficult and suspect. CTFA advised that the best we could do was to ask Dr. John Hopkins to follow a process called “Self-Nomination” and offer his name to IARC as a talc expert. I have asked John to do this and he agreed. . . . CTFA also advised that Dr. Muscat is already involved with another IARC committee. Dr. Muscat and Huncharek are experts that are working with us on white papers for NTP and whom we respect. CTFA will ask Dr. Muscat and Huncharek to also self nominate for IARC.

101. In July 2005, Mann’s email was forwarded to additional J&J personnel by Susan Nettesheim (“Nettesheim”), VP of R&D at Johnson’s Worldwide as of December 2005. Nettesheim said it was “[g]ood news that we may be able to have Hopkins work with IARC.” Among the individuals receiving Nettesheim’s email was Neal Matheson (“Matheson”), Chief Technology Officer of J&J Consumer Companies from 1994 to 2007 and again from 2012 to 2014. Showing particular interest in the talc issue, Matheson forwarded the email chain back to Mann on August 29, 2005, asking “Anything new on this?” Mann reported to Matheson and Caselvieri, among others, that Hopkins and another J&J consultant were not invited to participate in the IARC process, but that Muscat, “one of the epidemiologists that worked with us in 2000[,] has been asked to participate.” Mann explained why it was important having

Muscat in the IARC situation and reported back on his “latest intelligence” in the war with the NTP:

Dr. Muscat is currently working with Dr. Mike Huncarek, Luzenac and J&J on a couple of projects related to the NTP talc review. I am very pleased that Dr. Muscat will be involved in the IARC process as he has been very helpful to us.

My latest intelligence suggests that NTP is deferring to IARC for the moment, and may have even orchestrated IARC taking on the review of talc. We have not heard that NTP has even begun work on the Background Document for talc, thus this seems to confirm that they are waiting for IARC.

102. After delivering the good news to Matheson and Caselvieri, Mann had to admit later the same day that IARC “made a liar out of [him]” by rejecting Muscat’s self-nomination to the working group:

No sooner did I speak then IARC has made a liar out of me. I believed Dr. Muscat had been selected by IARC, because they had specifically asked him to submit. But, Josh [Muscat] just sent a copy of the attached letter he received to Rich Zazenski (Luzenac). IARC declined to include Dr. Muscat in the Working Group. IARC has become very sensitive about any industry connections.

Matheson then responded to Mann’s first August 29, 2015 update, asking Mann: “Any specific actions we should consider???” In a response also received by Caselvieri, Mann stated: “I thought we were in pretty good shape if Joshua was involved. I’m exploring what now? I’ll get back to you ASAP.”

5. Under the Direction of Defendant Casalvieri, J&J's Efforts to Defeat the NTP Prove Successful, but J&J Fails to Manipulate IARC

103. Although J&J was having little success against IARC, J&J finally defeated the NTP in October 2005, when the government withdrew talc from review for possible listing in the 12th RoC. An October 18, 2005 notice in the Federal Register shows that the NTP's reasoning echoed the "fatal flaw" strategy which assumed that asbestos was no longer in cosmetic talc like J&J's:

It has become evident that the literature on both forms of talc, with a few exceptions, provides an inadequate characterization of the actual materials under study to enable one to reach definitive conclusions concerning the specific substances responsible for the range of adverse health outcomes reported.

104. As alleged in ¶¶87-91, however, numerous current and former J&J employees knew that this "fatal flaw" was illusory, including Steve Mann, Sarah Colamarino, Lorena Telofski, John Hopkins, Marc Monseau, and Bill Ashton. The same day that the NTP withdrew talc from review, Mann sent a victory email to over 30 individuals including defendant Casalvieri, Hopkins, Matheson, Monseau, Telofski, and Wehner, as well as J&J's legal counsel, John O'Shaughnessy. In the celebratory message, *sent less than two years after he had learned of asbestos contamination in Johnson's Baby Powder*, Mann made clear that the NTP decision on talc was "a direct result" of J&J's efforts to manipulate the federal regulatory program:

Great news. NTP has withdrawn talc from consideration for listing on the 12th Report on Carcinogens. They also have not listed it for consideration on the 13th RoC, as they did for some other materials. Talc was the only material withdrawn.

This is a direct result of our efforts in coordination with Luzenac and CTFA. We did it!

In response, personnel at J&J congratulated themselves. Annie Heremans responded:

That is good work indeed and not the only achievement this group has made around topics of this nature this year. It all speaks to teaming up the best knowledge we have in the company efficiently.

And Gaetan Rouleau congratulated Mann and Casavieri specifically, telling them:

“Great job, this is a major accomplishment for J&J.”

6. J&J Is Again Warned of the Dangers Posed by Its Flagship Product

105. Despite J&J’s “major accomplishment” with the NTP, the Company soon found out that it had failed to influence the WHO, as the IARC working group concluded in February 2006 that perineal use of talc-based body powder is possibly carcinogenic to humans. Luzenac/Rio Tinto eventually included the IARC categorization in its talc’s Material Safety Data Sheet (“MSDS”). By late March 2006, the talc supplier was drafting new language for the MSDS and would soon begin discussing “a ‘mass distribution’ of the revised MSDS to [its] customers,” which Zazenski explained is “required when new and significant H&S data is reported.” By 2009, the MSDS from Luzenac regarding talc would include the following language under “Carcinogenic Status”:

IARC: (2006 in preparation) Has concluded that *perineal use of talc-based body powder is possibly carcinogenic to humans* (Group 2B). This is not a route of exposure relevant for workers and applies to one specific use of talc only.

IARC: (2006 in preparation) Inhaled talc *not containing asbestos or asbestiform fibres* not classifiable as a human carcinogen (Group 3)[.]

106. Along with the warning about ovarian cancer from J&J's talc supplier, one of the Company's own employees, Todd True ("True"), repeatedly sounded alarm bells. True, J&J's Global Creative Director, wrote a series of emails expressing concern over selling talc for use on babies. In an April 16, 2008 email, True recognized that Johnson's Baby Powder was not actually safe for babies and that it was therefore a "major contradiction":

Our current base talc product, although purchased primarily (80%) for adult use, is called "Baby Powder" and has instructions for use on baby on the back. *The reality that talc is not actually safe for use around babies is a major contradiction.*

Have we done any research to determine the potential negative impact to our brand or best for baby strategy by maintaining this ingredient? Have we looked at replacing talc with cornstarch for our base powder as other brands have? *What's the value in maintaining talc under baby aside from cost?*

107. In an April 18, 2008 email with the subject "Baby Powder – not for babies," True illustrated the "disturbing" reality "that talc is unsafe for use on/around babies" and proposed moving talc out of the baby line of products:

The reality that talc is unsafe for use on/around babies is disturbing. I don't mind selling talc, I just don't think we can continue to call it Baby Powder and keep it in the baby aisle.

* * *

Using Our Credo as our guide, I'd like to develop a strategy with you to eliminate the use of talc under Johnson's Baby.

108. And later on April 18, 2008, J&J's Global Creative Director True stated in an email that he was "on a bit of a mission to strongly consider removing talc from the baby aisle," although he knew it would be controversial since the Company would look to the "cost implications":

Basically, I'm thinking it would be in the brand's best interest to develop a strategy to move out of the baby aisle for our talc product and either create a direct Adult proposition or simply replace the talc ingredient with cornstarch. This would align with our Best for Baby charter.

I understand this is a \$70M business in the US alone, unsupported. So any changes are risky. However, given a number of other ingredient issues we are facing, this seems like an easy fix and win. I know this will be controversial and *we'll need to work hard to justify the cost implications* – I also see great positives associated with it in our challenge to maintain Mom's trust and deliver on our baby expertise.

109. But rather than work with its employee to improve the safety of the Baby product line, J&J sent an intimidating letter to True on May 19, 2008. In the letter from J&J's Ellen Kurtz ("Kurtz"), Director of Scientific Affairs at the Baby Care Franchise, True was cryptically told that his month-old email had "been given to [Kurtz]" and was chastised for making statements about the safety of talc that were "not accurate." It stated in part:

Dear Todd,

Your e-mail to Fred Tewell, dated 4/18/08 concerning baby powder has been given to me. I wish to respond to the concerns that you raised in that email about talc.

The statements that you made in that email about the safety of talc are not accurate and your recommendations do not reflect our company's involvement in and consideration of the scientific research and data regarding our talc used in JOHNSON'S® BABY POWDER. The safety and effectiveness of talc in baby powder has been shown extensively in numerous laboratory and clinical testing by JOHNSON'S® scientists and external scientific experts. In fact, babies, children and adults have safely used JOHNSON'S® BABY POWDER for over 100 years.

110. J&J was also warned through internal audits showing that the testing of its talc for asbestos was questionable at best. An April 13, 2012 J&J Contract Manufacturing Audit Report of the testing facility at RJ Lee, an outside testing company ("Audit Report"), found numerous problems with the lab, including the "[c]ritical" observation of evidence pointing to "***deficiencies in the document control process.***" Further, RJ Lee did not even have J&J's asbestos testing methods and was of the opinion that one of J&J's methods was not "optimal" anyway:

1. Did not have TM7164, were using IP2007. . . . Notes were being used in lieu of the testing requirements to perform test IP2007.
2. Specifications/SDPs/***Test Methods were not readily accessible for use at the point where required.*** More than one analyst was working from notes versus the testing document.
3. There were multiple revisions of J&J RM specifications in the storage drive that is to contain the most current revision of the specifications.
4. ***There was no current TM7024 for Asbestos*** [J&J's test method] at the site. ***RJ Lee also indicated that the test method was not an optimal method for asbestos testing.***

5. Operating inspections and calibration procedures need to have better clarity.

111. Just as alarming, the Audit Report noted that “particulate matter” was observed on equipment, “[t]here is *no formal quality agreement between J&J and RJ Lee*,” and “[t]here is *no overall housekeeping process that insures cleanliness in the facility and laboratories*.”

D. With Its Reputation on Thin Ice Because of Product Recalls and Ethical Lapses, the Company Makes Defendant Gorsky Its New CEO

112. On April 26, 2012, just a few weeks after the Audit Report showing that J&J’s outside testing facility was unreliable, defendant Gorsky became the new CEO of the Company. At that time, J&J had been having numerous issues with the quality of its products, as the Company had faced “about 30 recalls of consumer health products, hip replacements and prescription drugs,” for reasons that “included nauseating packaging odors, wrong levels of active ingredients in pills, and glass and metal shards in liquid medicines.” But while Gorsky was chosen to right the ship, he had a history of being deeply involved with troubling corporate misconduct.

113. For example, J&J eventually paid more than \$2.2 billion to resolve numerous allegations of targeting elderly and child patients with off-label marketing of Risperdal and two other drugs, as well as paying kickbacks to medical professionals and Omnicare Healthcare Corporation (“Omnicare”). According to the DOJ, Gorsky “was actively involved in matters at issue” in the government’s fraud case, including

having “multiple meetings” with Omnicare about promotion of Risperdal, as well as approving agreements to sell drugs to Omnicare.

114. A *Law360* article, entitled “J&J Inks \$2.2B Settlement For Off-Label Marketing, Kickbacks,” illustrated the DOJ’s opinion of the conduct that occurred under defendant Gorsky’s leadership:

DOJ depicted that behavior as *especially unscrupulous* because the [FDA] had expressly refused to approve Risperdal for dementia and because patients with [dementia] were known by 2003 to be more susceptible to strokes when using [Risperdal].

In fact, J&J and Janssen even went so far as to dilute alarming data from clinical trials

Further, Janssen ignored its own data showing . . . an increased risk of diabetes

Janssen managers effectively embraced off-label promotion

According to the government, Janssen “‘recklessly *put at risk the health of some of the most vulnerable members of society*’” and showed “‘*blatant disregard for systems and laws* designed to protect public health.’”

115. Nor was Risperdal the only time that Gorsky was involved with such behavior. For example, while at Novartis, Gorsky received a warning letter from the FDA regarding the drug Exelon that pointed to misleading risk presentations and other violations that “‘suggest[ed] that Exelon is safer . . . than has been demonstrated’” and encouraged use of the drug “‘in circumstances other than those for which the drug has been shown to be safe and effective.’” And Gorsky was eventually forced to sit for a

deposition in litigation surrounding DePuy Orthopaedics, Inc. (“DePuy”) Pinnacle hip implants, as the court reasoned that Gorsky had “personal involvement in the preparation of press releases and other official statements for the Pinnacle Device, presentation of information about the Pinnacle Device to medical professionals, and preparation of responses to news articles regarding recalls of other DePuy hip implants.” In December 2016, a Texas federal jury ordered J&J and DePuy to pay over \$1 billion.

116. By the time Gorsky became CEO of J&J in April 2012, both the Company and Gorsky himself were well aware that the questionable nature of J&J’s conduct and quality control were on the minds of investors and the media. Indeed, on his very first day as CEO, Gorsky faced questions from investors upset about J&J’s “battered image amid unprecedented product recalls and ethical lapses.” At J&J’s annual meeting, the investors “peppered its new CEO with questions and criticism,” and “raised concerns over serious side effects of some J&J prescription medicines.”

117. To alleviate shareholder concerns, Gorsky and his predecessor “repeatedly stressed that J&J is sticking to the values in its corporate Credo, which puts patients, doctors, nurses and employees ahead of profits.” In fact, Gorsky assured investors that he was ““resolute in his determination to keep our credo as the foundation for Johnson & Johnson.”” Spending “more than 30 minutes reviewing the venerable tenet, interspersing each passage” with a short story, “it was as if the

company was reaching into a pocket . . . to prove to investors that it had not lost its way.” Despite these assurances, Gorsky knew that concerns about J&J’s quality issues remained. Indeed, one attendee asked if Gorsky and J&J were going to take action ““to ensure that Johnson & Johnson continues to be the honorable company that it’s always been,”” while another expressed his hope that Gorsky would ““lead us back to the point where we will all be happy to hear the name Johnson & Johnson on the evening news.””

118. Gorsky and J&J had received this message loud and clear, and on September 13, 2012, the Company announced that “corporate fixer” Sandra Peterson would join J&J on December 1, 2012 in order to oversee the consumer unit and Global Supply Chain, along with Information Technology. The decision to bring in defendant Peterson was especially noteworthy, as it was the first time in the Company’s history that it had invited an outsider to join its executive committee rather than promoting from its own ranks. In an article entitled “J&J Recruits Bayer Executive,” the *Wall Street Journal* would report:

Ms. Peterson’s hiring is the first major personnel move by new Chief Executive Alex Gorsky since he took the helm in April. It is also a departure from J&J’s tradition of looking inward to fill the ranks of executives.

People familiar with Mr. Gorsky’s thinking say he believes J&J could benefit from an outsider’s perspective, and the hire ***shows the premium he puts on fixing the consumer and supply chain issues once and for all.***

* * *

Mr. Gorsky wooed Ms. Peterson for several months, according to a person familiar with the hiring. J&J completed its pursuit of Ms. Peterson in late August, when she accepted its proposed pay package and told Bayer, another person said.

119. But as the events of the Class Period would show, Peterson could not fix the Company's troubling history of knowingly exposing babies and mothers to a potent carcinogen and conducting a well-orchestrated campaign to cover it up.

E. The Class Period Begins – in the Face of Lawsuits Linking Its Talcum Powder to Ovarian Cancer, J&J Conceals the Company's True Litigation Exposure and Reputational Risk

120. At the same time that Gorsky, Peterson, and J&J were working to retain the trust of investors and consumers, the Company was beginning to face litigation brought by consumers alleging that the talc in J&J's Baby Powder and Shower to Shower products had contributed to their ovarian cancer. While these allegations concerned the talc itself, defendants knew that J&J's products were contaminated with asbestos, and that the Company's longstanding misinformation campaign to deceive and manipulate researchers and regulators was at risk. Were the truth to be revealed, it could prove devastating to the Company's efforts of preserving the public's trust.

As J&J's counsel admitted on June 6, 2018:

[Johnson's Baby Powder is] an important product because the signature of the founders are on every bottle. And they know that this is about trust. This is about the trust of Johnson & Johnson. Because they know that the people who use this product are mothers and babies. And these are Johnson & Johnson's customers. So this *is* about trust.

Facing the distinct possibility of old skeletons finally being dragged out of the closet, defendants made numerous false and misleading statements to investors and the public.

121. On February 22, 2013, the first day of the Class Period, J&J filed its 2012 Form 10-K with the SEC. Despite J&J's long history with asbestos contamination and continued failure to use proper testing methodology, defendants told investors that J&J "remain[ed] committed" to "improving existing products" and "delivering high quality":

Research activities represent a significant part of the Company's businesses. Research and development expenditures relate to the processes of discovering, testing and developing new products, ***improving existing products***, as well as demonstrating product efficacy and regulatory compliance prior to launch. ***The Company remains committed to investing in research and development with the aim of delivering high quality*** and innovative products.¹¹

122. Defendants also represented that the warnings and instructions accompanying the Company's products were adequate:

Certain subsidiaries of Johnson & Johnson are involved in numerous product liability cases. The damages claimed are substantial, and while ***these subsidiaries are confident of the adequacy of the warnings and instructions for use that accompany the products at issue***, it is not feasible to predict the ultimate outcome of the litigation.¹²

¹¹ Substantially similar fraudulent statements were also made in the Company's 10-Qs for the first, second, and third quarters of 2013.

¹² Substantially similar fraudulent statements were also made in the Company's 10-Qs for the first, second, and third quarters of 2013.

123. Then, on April 25, 2013, almost one year to the day after defendant Gorsky became CEO, J&J introduced a new corporate branding campaign at its annual shareholder meeting. Set to continue indefinitely and cost at least an estimated \$20-30 million, the branding campaign was part of J&J's efforts to "get past some of the challenges [it] had as a business." As defendant Sneed, J&J's VP of Global Corporate Affairs, admitted, "[t]he reputation of J&J is very important to us. We take it very seriously. We have a lot of data that we look at, both externally and internally."

124. But in working tirelessly to protect that reputation, J&J also told investors that it had "*made great strides*" in "*really get[ting] past some of the challenges* we've had as a business." According to Sneed, the Company had "*really embraced transparency*," as it had "a great story to tell" and wanted to help people "*understand the values behind J&J*" and "*make sure we have a full conversation about who J&J is*." Sneed boasted of J&J's admirable conduct, assuring investors that "*when we do make mistakes, we own up to those mistakes*." And according to Sneed, the new ad campaign focused on "*what people do when they care unconditionally for others*," which "*comes out of the history of J&J*."

125. J&J further boasted of its "quality initiative" during a July 16, 2013 conference call regarding the Company's results for the second quarter of 2013 ("2Q13"). According to defendant Peterson, J&J's "quality effort [was] across the

enterprise, across all of our businesses,” since J&J was “trying to ensure that we have the highest standard of quality for the safety and care of our patients and consumers.” In addition, Peterson promised that “as we’ve gone through all of this work, ***we have identified corrective actions, and we’ve immediately taken those corrective actions.***” Peterson also told investors that “early warning systems” were being put “in place” so that ***“if we think there may be something going on with a product,” “we identify it early and we go out and correct it.”*** Finally, Peterson assured investors that the Company was “ensuring that all of our external suppliers . . . are thoroughly reviewed, are thoroughly managed, and that they are living up to our quality standards.”

126. Then, in October 2013, J&J experienced the first jury verdict in favor of a plaintiff linking J&J’s purportedly “asbestos-free” baby powder to ovarian cancer. While the jury did not award damages, J&J knew it could face a “furor” from the public if it were revealed that the Company’s powders contained asbestos. In order to maintain its fraudulent scheme, J&J emphasized the safety of its talc on its “Our Safety & Care Commitment” website.¹³ Defendant Goodrich personally worked on the language to be included on the website regarding talc. Indeed, an internal J&J

¹³ The web address for this web page was <http://www.safetyandcarecommitment.com:80/ingredient-info/other/Talc>. A “capture” of the webpage as it appeared on January 7, 2014 was accessed through the Internet Archive, located at archive.org/web. The historical page says it “was last modified on December 11, 2013.”

document that was created on October 7, 2013, with the filename “Talc website copy 10 7 13.doc” was modified by defendant Goodrich and was also held in her files. *See* Ex. 2.

127. According to J&J and defendant Goodrich on the website, “[f]ew *ingredients have demonstrated the same performance, mildness and safety profile as cosmetic talc, which has been used for over 100 years*” and has “*a long history of safe use.*” J&J and Goodrich also assured investors and the public that J&J’s “*talc is carefully selected, processed and tested to ensure that [it] is asbestos free*” and that this has been “*confirmed by regular testing conducted since the 1970s.*”

128. But J&J’s own internal draft of this language, held in the files of defendant Goodrich, illustrates its false and misleading nature. In fact, while the website represented that cosmetic talc had “a long history of safe use” after being “used for over 100 years,” the draft language had actually refuted this claim and recognized that the use was not safe, as the copy for the website contained the following edit: “Talc has over 100 years of ~~safe~~ use in personal care products.” In addition, the copy for the website admitted that “*I don’t think we can link cosmetic talc to 100 years of use.*” Finally, the draft language contained the admission that when it came to J&J’s “talc-based consumer products,” J&J “cannot say [they have] ‘always’” been asbestos free.

DRAFT 1 – Copy for SafetyandCareCommitment Website

On Home Page of SafetyandCareCommitment.com website, at bottom right, under Key Topic, replace Microbeads with the following copy:

Key Topic

Talc has over 100 years of ~~safe~~ use in personal care products. Learn more ...

(Link to Ingredient Policies page, insert new item under “Other Materials” and after “Triclosan”, copy to read)

Talc**The Use of Cosmetic Talc in Personal Care Products**

Few ingredients have demonstrated the same performance, mildness and safety profile as cosmetic talc, which has been used for over 100 ~~(I don't think we can link cosmetic talc to 100 years of use)~~ years by millions of people around the world. Talcum powder is made from the mineral, talc. In a powder form, talc helps reduce friction, making it useful for keeping skin dry and helping to prevent rashes. Talc is a common ingredient found in cosmetic products such as baby powder and adult body and facial powders, and in a range of other consumer products such as toothpaste, chewing gum, and aspirin.

JOHNSON'S® talc products are made using U.S. Pharmacopeial (USP) grade talc to ensure it meets the highest-quality, purity and compliance standards. Our talc-based consumer products ~~are have always been~~ ~~(we cannot say “always”)~~ asbestos free, as confirmed by regular testing conducted since the 1970s. We also make JOHNSON'S® Baby Powder that contains cornstarch.

129. In addition, defendants knew of but failed to disclose the many findings of asbestos in J&J's talc and powders, J&J's efforts to remove tremolite from its talc, and the Company's continued failure to use proper testing techniques.

130. In further support of the Company's flagship product, J&J and Goodrich boasted on the website that “more than 30 years of research by independent researchers, scientific review boards and global regulatory authorities” supported the Company's purported “confidence in using talc.” The website further emphasized that “[v]arious agencies and governmental bodies have examined whether talc is a

carcinogen” and that “none have concluded that it is.” Finally, defendants relied on the purported “[m]any research papers and epidemiology studies” that “have been published since the early 1990s,” representing that “*these studies have found talc to be safe.*”

131. But these promises were also false and misleading. While J&J and Goodrich asserted that “more than 30 years of research” supported the safety of talc and that studies “since the early 1990s . . . have found talc to be safe,” they omitted what they recognized internally – that there were other scientific sources that were not included on the website because “they [were] not as definitive or supportive and could be interpreted as suggesting a causal effect,” including from such preeminent organizations as the American Cancer Society and IARC. *See* Ex. 2. Indeed, in the draft language for the website, a “NOTE TO CAROL/JAY” specifically informed defendant Goodrich that “[e]ven some of the studies we cite send mixed messages.” Goodrich was even informed that one of the studies cited by J&J actually acknowledged that “*perineal talc use may modestly increase the risk of invasive serous ovarian cancers.*”

NOTE TO CAROL/JAY: Besides those below, there are other links to consider, but they are not as definitive or supportive and could be interpreted as suggesting a causal effect, such as the American Cancer Society and IARC. Even some of the studies we cite send mixed messages. For example, Gertig et al concludes:
 “Our results provide little support for any substantial association between perineal talc use and ovarian cancer risk overall; however, perineal talc use may modestly increase the risk of invasive serous ovarian cancers.”

132. In addition, the representations by J&J and Goodrich on the website regarding “more than 30 years of research” and “agencies and governmental bodies” supporting the safety of talc were false and misleading because they omitted J&J’s longstanding scheme to influence and manipulate researchers and regulators, as well as J&J’s knowledge of asbestos in the Company’s talc and powders.

133. Along with J&J’s “Our Safety & Care Commitment” website, defendants continued to cover up its true reputational risk and litigation exposure through investor calls and SEC filings. On a January 21, 2014 conference call regarding J&J’s fourth quarter of 2013 (“4Q13”) and Fiscal Year (“FY13”) results, defendant Gorsky promised that J&J had been “*doing whatever it takes to ensure that we continue to earn the trust of consumers and patients around the world.*” He also boasted that J&J’s “*Chief Medical and Chief Quality Officers are setting new benchmarks for medical safety,*” which included a new approach to “*monitoring the use of our end market products*” to “*ensur[e] that they are safe.*”

134. These statements were false and misleading and omitted material information. While Gorsky claimed that J&J had been “doing whatever it takes” to earn the trust of consumers, including ensuring the safety of the Company’s products, the truth was that defendants were continuing the Company’s longstanding fraudulent scheme by concealing the asbestos contamination and J&J’s purposeful campaign to influence and manipulate regulators and scientists.

135. And on February 21, 2014, J&J filed its 2013 10-K with the SEC (“2013 10-K”), again representing that J&J was “improving existing products” and that the Company “remain[ed] committed” to “delivering high quality.”¹⁴

F. As Ovarian Cancer Litigation Spreads, Defendants Continue to Conceal J&J’s True Reputational and Litigation Exposure

136. Talc-related litigation against J&J began to increase in 2014, as two federal class actions were filed in May of that year, alleging that the Company failed to warn of health risks associated with its talcum powder products. And by June 2014, J&J faced similar allegations brought by the Attorney General of Mississippi, as well as in an action filed on behalf of dozens of plaintiffs in Missouri state court. With claims regarding ovarian cancer mounting, defendants stepped up their efforts to conceal J&J’s true reputational and litigation exposure stemming from the Company’s longstanding knowledge of asbestos contamination, as well its decades-long campaign to cover it up.

137. During a JPMorgan Healthcare Conference on January 12, 2015, defendant Gorsky promised that J&J’s “*number-one priority in dealing with patients and consumers*” was “[q]uality and safety” and that “over the last few years,” *J&J had “addressed any of the outstanding issues that we were facing.”*

¹⁴ The same or substantially similar fraudulent statements were made in the Company’s Form 10-Ks for 2014 and 2015, as well as in the Company’s Form 10-Qs for the first and second quarters of 2014.

138. Then, on February 5, 2015, defendant Glasgow posted to a webpage from J&J entitled “Making Every Moment Matter,” where she boasted that J&J was “*tak[ing] our research to the next level by looking at all the science . . . that help our babies thrive and grow.*” According to Glasgow, VP of R&D at JJCI, J&J was looking at ways to “make the little moments – like bath time” “mean *so much more*” through nurturing “your baby’s ability to learn.”

139. A few months later, at an April 23, 2015 Shareholders Meeting, defendant Gorsky set out to defend J&J’s reputation as the “Baby Company” by assuring investors that J&J was “committed to helping mothers and babies”:

Johnson & Johnson is committed to helping mothers and babies, we never want to forget the needs of the world’s smallest patients.

* * *

[C]aring inspires us day in and day out as we strive to make a difference for people who count on us the most. And as the world’s largest and best healthcare company in the world, we’re committed to reaching more people in more places in more ways. We’re helping people ultimately live longer, healthier, and happier lives.

140. These statements were false and misleading and contained material omissions. In truth, rather than making sure that J&J had “addressed” the countless disturbing facts regarding Johnson’s Baby Powder, defendants continued the Company’s longstanding fraudulent scheme in order to protect J&J’s flagship product by concealing the presence of dangerous asbestos. As Gorsky admitted during the April 23, 2015 Annual Shareholders Meeting, “our consumer, our iconic consumer

brands have been, and continue to be, perhaps *the greatest connection that we have with people*, with consumers all over the world.”

141. While defendants boasted of (i) providing parents “an opportunity to nurture [their babies’] ability to learn,” (ii) being “committed to helping mothers and babies,” and (iii) “helping people ultimately live longer, healthier, and happier lives,” they omitted that J&J had knowingly provided parents the opportunity to unwittingly expose their babies to a known carcinogen. And although defendants represented that “[q]uality and safety” were J&J’s “number-one priority,” they omitted J&J’s longstanding fraudulent scheme and storied history of prioritizing the *image* of its Baby Powder’s safety, rather than addressing the reality of its Baby Powder’s asbestos contamination. Similarly, while Glasgow represented that J&J was “looking at all the science . . . that help our babies thrive and grow,” the truth was that J&J continued to disregard the numerous findings of asbestos in its talcum powder and failed to implement adequate asbestos testing methods.

142. By December 25, 2015, J&J had updated its “Our Safety & Care Commitment” webpage regarding talc.¹⁵ Even though J&J had admitted internally that cosmetic talc could not be linked to 100 years of safe use, defendants emphasized

¹⁵ The web address for this web page was <http://www.safetyandcarecommitment.com/ingredient-info/other/talc>. A “capture” of the webpage as it appeared on December 25, 2015 was accessed through the Internet Archive, located at archive.org/web. The historical page says the “site was last modified on December 10, 2015.”

the “long history of safe use” of talc and promised that “[w]ith over 100 years of use, few ingredients have the same demonstrated . . . safety profile as cosmetic talc.” And despite the Company’s internal knowledge of asbestos contamination, defendants claimed that it was a “*misperception[]*” “*that talc products contain asbestos.*” Defendants even referenced J&J “ask[ing] outside experts for an independent perspective” and “carefully assess[ing] all available data on talc,” but claimed that based on this review, consumers “can feel confident” in the safety of talc. In truth, defendants knew or recklessly disregarded J&J’s history of asbestos contamination in its talc and powders. Rather than disclose the truth, defendants boasted on the “Our Safety & Care Commitment” website that the talc used for J&J’s products “is *carefully selected and processed to be asbestos-free,*” and that J&J “*confirm[s] this with regular testing.*” They even promised that J&J’s talc products are “precisely mill[ed]” “to decrease the potential to be inhaled or absorbed into the body,” while failing to disclose that the talc and powders had repeatedly been found to contain asbestos.

143. In addition, J&J continued to rely on the defenses it had worked so hard to create over the previous decades, claiming that “more than 30 years of research by independent scientists, review boards and global authorities” supported the safety of talc, omitting J&J’s longstanding scheme to influence and manipulate researchers and regulators and its internal recognition that the science was unclear at best. Indeed,

while defendants relied on the FDA, they failed to disclose that J&J had assured the FDA that no asbestos had been detected when in fact J&J insiders had acknowledged the asbestos contamination. Similarly, defendants boasted that “[c]osmetic talc is not included in the most recent Report on Carcinogens,” but they omitted the Company’s own admission that talc’s absence from the RoC was a “direct result” of J&J’s efforts at influencing the process. And despite J&J’s knowledge that its Baby Powder was contaminated with asbestos, defendants falsely claimed that talc used in consumer products “is required to be asbestos-free and has been since the 1970s.”

144. J&J’s updated “Our Safety & Care Commitment” website also contained a personalized statement from defendant Casalvieri. According to Casalvieri, she and J&J “*want[ed] to assure women and caregivers who use our talc products that numerous studies support its safety,*” including “*assessments by external experts in addition to our company testing.*” Casalvieri emphasized that the “[m]any research papers and epidemiology studies [that] have specifically evaluated talc and perineal use” “have found talc to be safe.”

145. But Casalvieri’s assurances were false and misleading. In relying on “numerous studies” supporting the safety of J&J’s talcum powders, Casalvieri failed to mention the numerous occasions of asbestos being found in the Company’s talc and powders and J&J’s tireless efforts to influence the literature and regulators – information that she knew or recklessly disregarded as the person with *direct*

oversight over the continuation of these efforts in 2005. Indeed, a February 2005 email chain illustrates that *Casalvieri was directing the project which was “active to defend talc,”* with Mann handling the “day-to-day” activities.

146. While Casalvieri claimed that “external experts” supported the safety of talc, she failed to disclose that *J&J had “work[ed] with Luzenac and outside epidemiology experts to develop documents that scientifically support the lack of a relationship of talc and ovarian cancer”* – efforts that she had been informed of through a February 2005 email. Similarly, she was informed through an August 2005 email that Muscat, one of the authors of the secretly funded study, had worked with J&J back in 2000 and that Muscat was working with “Huncharek, Luzenac and J&J on a couple of projects related to the NTP talc review.” And an October 2004 email informed Casalvieri of some of the details of Luzenac’s Rich Zazenski’s “history with J&J on defending talc,” including the submission of analysis “under CTFA letterhead” to Dr. Olden of NTP. The email further informed Casalvieri that Zazenski had written a paper with J&J’s Ashton and Chudkowski for a workshop with the International Society of Regulatory Toxicology and Pharmacology/FDA about “the 1992 NTP Inhalation Study and growing concerns about the association of talc and ovarian cancer.” In the October 2005 celebratory email about the NTP withdrawing its consideration of talc, J&J’s Gaetan Rouleau *congratulated Casalvieri specifically*, along with Mann, as the NTP’s withdrawal of talc from consideration was “a major

accomplishment for J&J.” Finally, on the website, Casalvieri admitted that it was her job ““to make certain a product is safe by assessing whether any ingredient in that product poses a risk.””

G. After a Jury Finds J&J Liable for Damages in an Ovarian Cancer Lawsuit, Defendants Continue to Lie to Investors and the FDA

147. In February 2016, a Missouri state jury returned a verdict against J&J for failure to warn, negligence, and conspiracy and awarded \$72 million in damages to the estate of Jacqueline Fox, a long-time user of J&J’s talcum powders and a victim of ovarian cancer. This verdict was reportedly the first to award damages to a plaintiff linking ovarian cancer and J&J’s talc products, and it included an award of \$62 million in punitive damages. Rather than disclose its longstanding fraudulent scheme, J&J continued to cover it up.

148. In a February 23, 2016 *Reuters* article about the recent verdict, defendant Goodrich stated, “*“We . . . firmly believe the safety of cosmetic talc is supported by decades of scientific evidence.”*” And on February 24, 2016, J&J created a page on its website, entitled “The Facts About Talc Safety,” which made the familiar claim that “[w]ith over 100 years of use, few ingredients have the same demonstrated . . . safety profile as cosmetic talc.” But as alleged above, defendants J&J and Goodrich knew that cosmetic talc could not be linked to 100 years of safe use. ¶128. On the website,

J&J presented numerous other false and misleading statements as purported “[f]acts” about talc, including the following:

- “JOHNSON’s talc products do not contain asbestos.”
- It is a “misperception . . . that JOHNSON’s Baby Powder contains talc made with asbestos.”
- “Since the 1970s, talc used in consumer products has been required to be asbestos-free.”
- “The grade of talc used in cosmetics is of high purity . . . and is free from asbestos and asbestiform fibers.”
- “Cosmetic grade talc is only mined from select deposits from certified locations”
- “Cosmetic grade talc is . . . milled to relatively large, non-respirable particles size.”
- “Our sources for talc undergo comprehensive qualification.”
- “The incoming talc is routinely evaluated”
- “The incoming talc is . . . evaluated using a sophisticated battery of tests designed to ensure quality, safety, and compliance with all global standards.”
- “The safety of talc is based on a long history of safe use and decades of research by independent researchers and scientific review boards.”

149. Once again, these statements were materially false and misleading. In truth, (i) J&J had acknowledged asbestos contamination of its talc and talcum powders, (ii) J&J had tried to find a way to remove the tremolite from its talc, (iii) J&J purposely failed to use concentration methods that were required to actually detect the asbestos, and (iv) J&J had successfully influenced and manipulated regulators and

researchers in order to defend the talc's safety image. Furthermore, defendant Goodrich knew through her work on the "Our Safety & Care Commitment" website that "[t]he safety of talc" was not supported by "decades of research," as some sources "could be interpreted as suggesting a causal effect" and "[e]ven some of the studies [cited by J&J] send mixed messages." ¶131.

150. At the same time that J&J was misleading investors and the public regarding its talcum powder products, the Company continued its decades-long scheme to mislead and influence regulators. On February 25, 2016, only a few days after the \$72 million verdict against J&J, the FDA made the following written request to JJCI:

"Please provide all safety literature and data regarding talc, including data in support of the safety of this active ingredient and data that shows potential harmful effects for this active ingredient, by March 17, 2016."

151. J&J responded to this request on March 17, 2016 through a letter from Jethro Ekuta, VP of Regulatory Affairs North America at JJCI. In the letter, J&J addressed asbestos specifically, claiming that "[n]o asbestos-form structures have ever been found during any testing" of JJCI Body Powders:

For Body Powders, JJCI uses talc which meets the USP monograph. . . .

The USP permits the use of either Infrared Absorption or X-Ray Diffraction to evaluate for asbestos-form structures. If positive results are obtained, then Optical Microscopy is used as the definitive test. JJCI uses a combination of X-Ray Diffraction, Optical Microscopy, and Transmission Electron Microscopy (TEM).

As a second impurity check, talc used worldwide for J&J Body Powders is periodically sent to an independent test lab for a full comparative evaluation. *No asbestos-form structures have ever been found during any testing.*

152. This response to the FDA was false and misleading, as it omitted that J&J had been told repeatedly that its talc and talcum powders contained asbestos.

153. In its submission to the FDA, J&J also boasted that “[c]osmetic talc is not included in the most recent (2014) Report on Carcinogens, published by the US NTP.” But J&J omitted what it had admitted internally – that the NTP’s withdrawal of talc as a possible candidate for the Report on Carcinogens was “a direct result” of J&J’s teaming with its industry cohorts to manipulate the process.

154. J&J also told the FDA that its “confidence in using talc [was] based on more than 100 years of safe use and more than 30 years of research by independent researchers, scientific review boards and global regulatory authorities.” But J&J omitted what it had acknowledged internally – that “we cannot say ‘always,’” talc could not be linked to 100 years of safe use, and studies actually sent “mixed messages” on the association between talc and ovarian cancer.

H. As J&J Is Hit with Additional Ovarian Cancer Verdicts, Defendants Continue to Conceal the Asbestos Contamination and the Company’s Longstanding Fraudulent Scheme

155. On May 2, 2016, another Missouri jury found J&J liable in an ovarian cancer case, awarding \$55 million in damages. With knowledge of J&J’s decades-

long conspiracy to cover up the asbestos contamination of its Baby Powder, defendants again went on the offensive, promising that they “*remain[ed] completely confident*” that the Company’s talc was safe and that *J&J has done “the things you expect from a company you trust.”*

156. On the same day as the verdict, defendant Goodrich and J&J announced that the Company would appeal the jury’s decision, which purportedly “[went] against 30 years of studies by medical experts around the world that continue to support the safety of cosmetic talc.” But as alleged in ¶131, J&J and Goodrich knew that some of the information worth considering “could be interpreted as suggesting a causal effect” between talc and ovarian cancer, including from the American Cancer Society and IRAC, and that some of J&J’s own sources sent “mixed messages.” And while J&J and Goodrich claimed that “[m]ultiple scientific and regulatory reviews have determined that talc is safe for use in cosmetic products and the labeling on Johnson’s Baby Powder is appropriate,” they failed to disclose J&J’s exhaustive efforts to monitor and influence regulators and research in order to protect the safety image of the Company’s flagship product.

157. Also on May 2, 2016, J&J published “A Message About Talc” on its website. There, defendants represented that J&J has never had any doubts about potential hazards with its talc, as the Company “first offered” its Baby Powder “more than 100 years ago because we were confident in the safety of talc,” and defendants

“remain[ed] completely confident in its safety.” In truth, however, defendants knew that J&J had been repeatedly informed of asbestos in the Company’s talc and talcum powders and that the Company had worked tirelessly to conceal this information for decades.

158. J&J’s “Message About Talc” was also false and misleading for numerous other reasons. According to defendants, J&J “has always taken questions about the safety of our products extremely seriously.” Recognizing that “families have trusted” Johnson’s Baby Powder “for generations,” defendants represented that “[w]hen concerns about . . . talc and ovarian cancer were first raised,” *“Johnson and Johnson took them very seriously and did the things you expect from a company you trust.”*

These activities purportedly included:

- Testing to ensure that the talc in JOHNSON’S® Baby Powder meets the highest Quality standards (US Pharmacopeia);
- Engaging with the FDA, regulatory agencies, and governments around the world;
- Monitoring studies and all available information examining the safety of talc; and
- Talking with independent consultants from outside our company about their point of view on the safety of talc.

159. In truth, J&J had acted in a manner vastly different than what any reasonable person would “expect from a company you trust.” As detailed above, while J&J did test its talc, the test methods chosen were purposely inadequate and unable to detect trace amounts of asbestos. And while J&J “[e]ngag[ed]” with

regulatory bodies and consultants and “[m]onitor[ed] studies,” defendants omitted that J&J had long conducted these activities to influence such work, which would prevent the regulators and scientists from discovering the truth about J&J’s flagship product. Defendants also failed to disclose that “all available information examining the safety of talc” included the repeated findings of asbestos contamination and the Company’s fraudulent scheme going back decades.

160. J&J also again relied on the defenses it had been orchestrating for decades – boasting that the safety of its talc was supported by “30 years of studies by medical experts around the world, science, research and clinical evidence.” But defendants once again omitted any mention of J&J’s longstanding scheme as well as the recognition internally that many of the studies were mixed when it came to talc safety. According to defendants’ “Message About Talc” website, “various governmental and non-governmental agencies as well as other expert panels have reviewed and analyzed all available data, and none have concluded that talc can cause cancer.” But defendants failed to disclose that J&J had made misleading statements to the FDA less than two months prior to the website posting, as well as that none of the agencies or panels were informed of J&J’s long history with asbestos contamination.

161. On May 10, 2016, J&J filed its Form 10-Q for the first quarter of 2016 (“1Q16”). There, defendants disclosed that the Company faced personal injury litigation relating to the Company’s talcum powders and that the Company had

established an accrual for the defense costs. But defendants failed to disclose the repeated findings of asbestos in the Company's talc, J&J's efforts to remove tremolite from its talc, the Company's purposely inadequate asbestos testing, or J&J's longstanding scheme to influence and manipulate regulators and scientists.¹⁶

162. With the ovarian cancer litigation receiving attention, J&J insisted on defending Johnson's Baby Powder. On May 18, 2016, Josh Ghaim ("Ghaim"), the Chief Technology Officer of JJCI, assured investors that "***we're being very careful in terms of what raw materials we select, what type of safety studies that are needed.***"

163. And in a June 19, 2016 *Houston Chronical* editorial, defendant Glasgow repeated many of the false and misleading statements made earlier. This included the promise that J&J had done "the things you expect from a company you trust" when concerns about ovarian cancer were raised, such as testing, meeting with regulators, "looking closely at the studies and available information" and "talking with independent consultants." She also boasted of the "purity" of J&J's talc, which is "carefully select[ed]" and "process[ed] . . . to be asbestos-free," as "confirmed . . . with regular testing since the 1970s." And she claimed that 30 years of scientific studies and regulatory reviews have shown" that "[c]osmetic talc is safe."

¹⁶ Substantially similar fraudulent statements were made in J&J's Form 10-Qs for the second and third quarters of 2016, and the first three quarters of 2017 and 2018, as well as in J&J's Form 10-Ks for 2016 and 2017.

164. But Glasgow’s editorial also made new, more personal promises about J&J and the safety of its talc. For example, she promised:

As a scientist, and most importantly, as a parent, ***I can tell you the science is clear – cosmetic talc is, and has been, safe for use and that is the most important guiding principle for every product*** Johnson & Johnson Consumer Inc. offers to consumers and patients.

165. As VP of R&D at JJCI, Glasgow also represented that J&J’s consumer division is “***guided by the medical facts and science when it comes to our products.***” In doing so, Glasgow omitted that J&J had long been guided by an intense desire to protect the safety image of talc and the Company, not by facts and science.

166. On August 4, 2016, J&J filed its 10-Q for the second quarter of 2016 (“2Q16”). There, J&J disclosed that it was not just its subsidiaries facing “numerous product liability claims,” but also J&J, the parent company. J&J assured investors it “ha[d] substantial defenses” itself.¹⁷

167. On December 30, 2016, J&J again touted the safety and effectiveness of talc in its products on the Company’s “Safety and Care Commitment” website, representing that because “[y]our trust in our products and your confidence using them every day is a huge responsibility,” ***J&J “only use[s] ingredients . . . deemed safe by***

¹⁷ The same or substantially similar fraudulent statements were made in J&J’s Form 10-Qs for the third quarter of 2016, and the first three quarters of 2017 and 2018, as well as the Company’s Form 10-Ks for 2016 through 2017.

the latest science.”¹⁸ Defendants also boasted that after having “*dug deep into the evidence and science on talc*,” they concluded that research, clinical evidence, “decades of science,” “and 30 years of studies by medical experts around the world” supported talc’s safety. But defendants omitted J&J’s own recognition of its talc being contaminated with asbestos, as well as the Company’s purposely inadequate testing. And while defendants assured investors and the public that J&J “take[s] any questions about our product’s safety seriously,” they failed to disclose that the Company had responded to those questions with a long campaign to monitor and infiltrate scientific and regulatory processes.

168. By January 24, 2017, J&J’s website entitled “The facts on talcum powder safety” contained a statement by defendant Glasgow that she and others at J&J had “assembled” and reviewed “all of the available data” regarding the safety of talc, which included “decades of conclusive, scientific, evidence-based findings.”¹⁹ Glasgow reemphasized that J&J valued safety and that “there is no information more important than our research on scientific data and safety.” According to Glasgow,

¹⁸ The web address for this web page was www.safetyandcarecommitment.com/Ingredients/Talc. A “capture” of the webpage as it appeared on December 30, 2016 was accessed through the Internet Archive, located at archive.org/web. The historical page says the “site was last modified on August 31, 2016.”

¹⁹ The web address for this web page was www.factsabouttalc.com. A “capture” of the webpage as it appeared on January 24, 2017 was accessed through the Internet Archive, located at archive.org/web.

based on “all of the available data,” “the science is clear: Cosmetic talc is, and has been, safe for use in consumer products.” And Glasgow promised that *talc “is safe to use as part of your personal care routine,” as shown by “decades of conclusive, scientific, evidence-based findings.”* In truth, however, J&J had not valued safety, as “the available data” showed that asbestos had been found in J&J’s talc and talcum powders numerous times and that the Company had intentionally used inadequate testing methods that were incapable of finding the asbestos in the Company’s talc.

169. On February 27, 2017, J&J filed its 2016 Form 10-K with the SEC. There, defendants included general language regarding the possibility of “[p]roduct efficacy or safety concerns” along with potential “declining sales and reputational damage,” such as “damage to brand image, brand equity and consumer trust in the Company’s products.” Among the many general risks and uncertainties faced by the Company, defendants listed “significant legal proceedings,” which could “result in significant expenses, fines and reputational damage.” At the same time, defendants repeated the mantra that J&J “believes it has substantial defenses.” Defendants also again represented that J&J was “improving existing products” and that the Company “remain[ed] committed” to “delivering high quality.”²⁰

²⁰ Substantially similar fraudulent statements were made in the Company’s 2017 Form 10-K, filed February 21, 2018.

170. Throughout these statements, defendants omitted the numerous findings of asbestos in the Company's talc and powders, the Company's attempts to remove tremolite from its talc, J&J's purposeful and continual rejection of adequate testing methods, and the Company's longstanding scheme to cover up the truth. Indeed, defendants simply listed the talc lawsuits as one significant area of litigation among many and claimed to have "substantial defenses," failing to disclose J&J's lengthy history of asbestos contamination. But while investors (and the public) were none the wiser, *the Company's Board of Directors was on high alert regarding the Company's sacred cow.*

171. A June 6, 2017 J&J email to the Board of Directors, including defendant Gorsky, illustrates that an entire slide deck with the heading "'Update on Talc Litigation'" and discussing "reputational risk" would be used during the June 12-13, 2017 Board and Committee Meetings:

To: Members of the Johnson & Johnson Board of Directors

Re: Materials for June 12-13 Johnson & Johnson Board and Committee Meetings

Materials for the June 12-13 Johnson & Johnson Board and Committee Meetings are now available for your review on the Board Portal. The following additional materials will be posted when they become available tomorrow:

- Ethicon/Hospital Medical Devices Update, including the Strategic Customer Transformation (the materials to be covered in the 9:15-10:15 review); and

- ***A second deck under the heading of “Update on Talc Litigation” in Tab 7 that discusses reputational risk.***

172. After coming out victorious for the first time in an ovarian cancer trial in March 2017, then losing yet another one in May 2017, J&J suffered its biggest loss yet in the first ovarian cancer verdict coming out of California. In August 2017, the jury in that case awarded the plaintiff a total of \$417 million in damages, including \$347 million in punitive damages.

173. The California verdict got the attention of financial analysts. For example, in an August 22, 2017 credit analyst note, “Johnson & Johnson’s Talcum Powder Legal Risk Heightens With Record Verdict,” Morningstar detailed the litigation J&J had, and still, faced:

On Aug. 21, a jury in the Superior Court of Los Angeles County awarded \$417 million in damages to a California woman who used Johnson & Johnson’s (rating: AAA, negative) baby powder over many decades and said that it caused her ovarian cancer and the firm failed to warn her of the possible risks associated with use of the product. The verdict is the largest handed out in the firm’s talcum powder product liability litigation thus far, but it is likely to be reduced upon appeal. However, ***this outcome is a harbinger of Johnson & Johnson’s growing exposure to the thousands of cases outstanding in the United States today.*** Four cases have already come to decisions in Missouri courts over the past year or so yielding total damage awards of approximately \$308 million, all of which are under appeal. ***These unfavorable results in the early trials may dictate the terms of a national settlement of the talcum powder product liability litigation,*** if the company were to pursue one. Presently, ***we see no negative effect on the current rating as the company has substantial liquidity to manage this caseload,*** with around \$13 billion in cash and short-term investments as of June 30 and free cash flow averaging nearly \$17 billion annually over the next five years, in our estimation.

174. In analyzing the caseload and a potential national settlement, Morningstar did not know about J&J's longstanding fraudulent scheme to conceal asbestos contamination, which would increase J&J's potential liability through additional lines of talc litigation, including lawsuits alleging that mesothelioma was caused by the asbestos, and lawsuits alleging that ovarian cancer was caused by the asbestos (rather than the talc itself).

175. The media also took notice of the litigation. For example, *The Star* newspaper published an article attempting to address the safety concerns, entitled "Does talcum powder cause cancer and should you stop using it?" The article quoted the oft-repeated mantra found on J&J's website, that "the safety of cosmetic talc is supported by decades of scientific evidence."

176. With the large verdict catching the attention of analysts and the media, defendant Gorsky was forced to address the talc litigation at a September 6, 2017 Wells Fargo Healthcare Conference. There, Gorsky assured investors that J&J always puts safety first and that the safety of talc was clearly demonstrated by clinical information, control data, and "100 years of experience." Gorsky also illustrated that he was paying close attention to the proceedings, as he went on to discuss events in specific jurisdictions and referenced "the data" providing the confidence in "the position that we're taking":

[W]e always put patient and consumer safety first in everything that we do. That being said, we think that the significant amount of clinical

information, control data in this category, both from agencies, such as the NCI as well as the FDA, clearly demonstrates the safety of talc, and by the way, from more than a 100 years of experience. That being said, we were disappointed with some of the early results, for example, in St. Louis. We're encouraged by some of the recent rulings out of Supreme Court regarding those venues. We've also been encouraged by some of the earlier findings in New Jersey. We were disappointed with the first outcome in California but, nonetheless, we feel that *we have some strong ground on the field going forward.* And again, *we remain, based upon the data, confident of the position that we're taking.*

177. Despite Gorsky's assurances, the Company had clearly not "always put patient and consumer safety first in everything" it did. Rather, J&J had concealed asbestos contamination of its talcum powders for decades. Indeed, even in 2017, rather than being focused primarily on safety risks, Gorsky and the other board members' primary focus regarding the talc litigation was on "reputational risk," as illustrated by the June 2017 email to the Board.

178. And while Gorsky again invoked the science and regulatory defenses the Company had spent decades building and boasted of having "some strong ground on the field going forward" "based upon the data" and "more than a 100 years of experience," he knew or recklessly disregarded that the Company's data actually showed repeated findings of asbestos contamination, J&J's attempts at developing methods to remove it, and the Company's purposeful use of inadequate testing methods, as well as the Company's successful efforts to manipulate regulators and researchers.

I. J&J Faces Its First Trial Involving Allegations of Asbestos in Talcum Powder Causing Mesothelioma

179. By September 2017, a trial was set to begin in a case against J&J brought by Tina Herford, who alleged that she had developed mesothelioma because of exposure to asbestos contained in J&J's talcum powder products through 1993 (the "Herford case"). As stated in a September 14, 2017 *Bloomberg* article entitled "Johnson & Johnson's Newest Talc Problem? Asbestos," it was "the first suit to go to trial alleging some J&J talc products made decades ago were contaminated with asbestos." Relying on analysis by Professor Jean Eggen of Widener University Delaware Law School, the *Bloomberg* article opined that "many more cases are likely on the way," but that they would be "both easier and harder to litigate" than the ovarian cancer cases or traditional asbestos cases. A key difficulty for the asbestos contamination claims would be proving "actual exposure to asbestos in the talc."

180. While the *Bloomberg* article contained the plaintiff's lawyer's representation that there was asbestos in the talc and that J&J hid the information, it also provided another lawyer's view that "the plaintiffs' scientists in these cases are engaging in 'pseudo-science.'" In addition, the article emphasized the Company's continued denials:

Johnson & Johnson declined to comment either on Herford's suit or the litigation generally. But a statement on the company's website says: "Since the 1970s, *talc used in consumer products has been required to be asbestos-free*, so *Johnson's talc products do not contain asbestos*."

What *Bloomberg* did not know, and what J&J continued to conceal, was that J&J's talc products had repeatedly been found to contain asbestos.

181. On September 21, 2017, *Bloomberg* published a second article entitled “J&J Was Alerted to **Risk** of Asbestos in Talc in ‘70s, Files Show.” Reporting on documents unsealed in a St. Louis ovarian cancer case brought by more than 50 women against J&J (the “Ingham case”), the article opined that the documents “add another dimension” to the St. Louis plaintiffs’ claims and noted that J&J was also facing over 5,000 ovarian cancer lawsuits nationwide:

The talc used by J&J to make its products “is not now, nor has it ever been, free from asbestos and asbestiform fibers,” according to the lawsuit filed on behalf of more than 50 women in St. Louis.

The unsealed documents add another dimension to the claims against J&J as it defends itself from more than 5,000 suits across the U.S. blaming its baby powder products for causing women to develop ovarian cancer.

182. The article cites a May 1974 recommendation by the director of research and development at J&J's Windsor mine that the Company use certain systems “to provide protection against what are currently considered to be materials presenting a severe health hazard and are potentially present in all talc ores in use at this time.” The article also discusses a 1973 J&J report stating that ““sub-trace quantities”” of two minerals are occasionally ““identifiable and these might be classified as asbestos fiber,”” as well as a training memorandum telling employees to assure anyone concerned about potential asbestos that the Baby Powder is asbestos free. Finally, it

discusses how in 1974, J&J got an Italian talc supplier to stop distributing English-language versions of a booklet mentioning trace amounts of asbestos in the talc, but the article also provides J&J's contention that testing at the Italian mine "showed no evidence of asbestos at the site."

183. In order to neutralize any concern over the released documents and convince investors that the St. Louis plaintiffs' theory was meritless, defendants insisted that Johnson's Baby Powder has *always* been free of asbestos. The *Bloomberg* article reported on J&J documents showing that "*tests of its talc stretching back to at least 1972 found no trace of asbestos*," along with the following assurances from J&J:

FDA Requirements

"The U.S. Food and Drug Administration requires specific testing to ensure that cosmetic talcum powder is free of asbestos," Ernie Knewitz, a spokesman for J&J, said in an emailed statement.

"We are confident that our talc products are, and always have been, free of asbestos, based on decades of monitoring, testing and regulation," Knewitz said. "Historical testing of samples by the FDA, numerous independent laboratories, and numerous independent scientists have all confirmed the absence of asbestos in our talc products."

* * *

New Brunswick, New Jersey-based ***J&J has said the plaintiffs' allegations aren't supported by valid scientific evidence***, pointing to a New Jersey state court decision last year tossing out two cases.

The unsealed files were used as part of an April pre-trial deposition given by Joanne Waldstreicher <<https://www.jnj.com/office-chief-medical-officer>>, J&J's chief medical officer since 2013. Under

questioning by plaintiffs' lawyer Mark Lanier, *Waldstreicher maintained that J&J's baby powder products are asbestos free. We have experts that assure there's no asbestos in our talc," she told the lawyer.*

J. J&J Continues to Defend Its Flagship Product, but the Truth Leaks Out

1. September 27, 2017 Disclosure

184. On September 27, 2017 a press release by Bernstein Liebhard LLP signaled to J&J investors that plaintiffs in ovarian cancer lawsuits throughout the country were looking to add asbestos allegations to their ovarian cancer claims. The press release, entitled "Talcum Powder Lawsuit Plaintiffs Claim Unsealed Documents Show Johnson & Johnson Knew of Talc-Asbestos Danger in 1970s, Bernstein Liebhard LLP Reports," stated in part:

Plaintiffs pursuing talcum powder lawsuits in Missouri state court claim that newly unsealed documents show that Johnson & Johnson has known since the 1970s that its talc-based powders contained asbestos fibers, which could increase the risk of ovarian cancer in women who used the products for daily feminine hygiene. (Case No. 1522-CC10417, Circuit Court, City of St. Louis, Missouri)

"Our Firm is representing women who allegedly developed ovarian cancer due to Johnson & Johnson's talcum powder products. *These documents are of great interest to our clients, and we will continue to monitor the Missouri litigation for any other developments that could impact their claims,*" says Sandy A. Liebhard, a partner at Bernstein Liebhard LLP, a nationwide law firm representing victims of defective medical devices, drugs and consumer products. The Firm is offering free legal reviews to women who were diagnosed with ovarian cancer that may be associated with Johnson & Johnson's Baby Powder and Shower-to-Shower products.

185. In response to the news, J&J's stock price declined from a close of \$130.94 on September 26, 2017 to a close of \$129.75 on September 27, 2017. An event study has determined that this decline was statistically significant.²¹

186. Analysts at Jefferies illustrated that the talc litigation was material to investors in an October 11, 2017 report in which they largely dispelled the concerns but noted that they would "continue to watch [the talc litigation] with interest":

Talc litigation still a focus for investors

We continue to receive questions on Talcum powder from investors given litigation in several different jurisdictions and relentless media attention on it. Whilst there are ongoing cases surrounding the potential cancer risks associated with talc, only a handful of cases have received a verdict. Johnson and Johnson have stated that they are not seeing a significant impact to the business and have highlighted that talc powder represents only 0.3% of sales on an enterprise basis. ***The FDA requires manufacturers of talc products to specifically take steps to avoid contamination with asbestos*** and that talc is used in a wide variety of other products including chewing gum, food processing, make up, soaps, pill manufacturing, antiperspirants, etc.

One of the highest profile rulings was in August 2017, where a California jury found in favour of the plaintiff and awarded \$70m in compensatory damages plus a further \$347m in punitive damages for a total of \$417m. ***Many investors have become nervous of the potential***

²¹ An event study isolates the stock price movement attributable to a company (as opposed to market-wide or industry-wide movements) and then examines whether the price movement on a given date is outside the range of typical random stock price fluctuations observed for that stock. If the isolated stock price movement falls outside the range of typical random stock price fluctuations, it is statistically significant. If the stock price movement is deemed statistically significant, it indicates that the stock price movement cannot be attributed to market and sector factors, or to random volatility, but rather was caused by new company-specific information.

size of total damages that could be awarded against Johnson & Johnson, given that there are approximately 6,000 women and their families suing the company. We note that in other cases, which have awarded damages against Johnson & Johnson the level of damages was generally much smaller. It should also be noted that Johnson & Johnson is seeking to appeal and overturn negative verdicts received to date and has won positive verdicts in some jurisdictions.

Scientific evidence appears to support JNJ on talc litigation

We note that Johnson & Johnson appears to have several large studies, as well as the FDA and National Cancer Institute on its side regarding the safety of talc. Against this, older studies in the literature have made associations between talc and ovarian cancer in women and the International Agency for research on Cancer classified talcum powder as a possible human carcinogen if used in the female genital area in 2006. A key point to some of the litigation to date has not been whether talc is carcinogenic, but as to whether Johnson & Johnson concealed evidence from the public that it might be.

Overall, we do not find the overall situation regarding talc litigation for Johnson & Johnson to be a major concern for us at present, though *we continue to watch it with interest*.

187. Adding to the confusion for investors, J&J obtained a victory in October 2017 when the \$417 million ovarian cancer verdict was thrown out by a judge in California. Then, on November 16, 2017, a jury in the Herford case returned a verdict in favor of J&J. Celebrating its victories, J&J once again touted that Johnson's Baby Powder does not contain asbestos.

188. Then, on January 16, 2018, *Fair Warning* published a story entitled "Baby Powder Battles: Johnson & Johnson Internal Documents Reveal Asbestos

Worries” (the “*Fair Warning* story”).²² The story was based on internal J&J memoranda and FDA documents showing that J&J was aware of the possibility of an issue with asbestos back in the 1970s. For example, *Fair Warning* referenced internal documents recognizing “*potential* asbestos content,” and occasional “sub-trace quantities” of what “*might* be classified as asbestos fiber.” It also references a 1974 document from J&J’s mining operation that recognized the need to ensure that asbestos was not present in the talc, as such materials were “a severe health hazard” and were “*potentially* present in all talc ores in use at [that] time.”

189. According to the *Fair Warning* story, while the documents “raise questions about J&J’s candor on the incendiary topic of asbestos and talc,” *they* “*don’t settle the safety issue.*” Indeed, in recounting “an asbestos scare” in the 1970s in which researchers “reported finding asbestos in a number of popular talc-based powders and cosmetics,” *Fair Warning* reported that “[i]t turned out that the reports of contamination were somewhat exaggerated.” *Fair Warning* also cited documents regarding J&J’s discussions with the FDA in the 1970s, along with J&J’s position in 1974 that *if* a baby powder contained 1% asbestos content, that would be a theoretically safe level of exposure as it “would be far less than the legal limit for an asbestos miner, the main standard then in place.” The *Fair Warning* story also

²² This story was republished by Salon.com on February 4, 2018.

reported that *J&J “has said its powders are perfectly safe, and could not have caused mesothelioma.”*

190. While the *Fair Warning* story focused almost exclusively on the 1970s “[w]orries,” it also mentioned that “[c]oncern has flickered over the years.” It cited Dr. Alice Blount’s 1991 paper in which she reportedly “said she had found asbestos fibers in some talc samples, including in a sample of Johnson’s Baby Powder.” But Blount had not actually identified which products had been tested in her 1991 paper, instead referring to them as Sample A through Sample O. It was only an unexplained, handwritten page at the end of the copy linked to by *Fair Warning* that decoded the samples in Blount’s paper, raising questions regarding the accuracy of the results reported by *Fair Warning*.

191. Importantly, the *Fair Warning* article emphasized J&J’s claims that asbestos had *never* been found in Baby Powder. Indeed, the *Fair Warning* story stated that the FDA had tested talc products and samples in 2009-2010, including Johnson’s Baby Powder, and that “[n]o asbestos was detected in any of the products or samples.” And while *Fair Warning* referred to purported asbestos findings by plaintiffs’ trial experts in mesothelioma cases “[t]argeting the deep pockets,” it also reported on J&J’s professed innocence:

Reports of asbestos contamination have [“]never been proven to be correct,” declared John Hopkins, a toxicologist and former J&J executive.

Defense lawyers made a plausible case for a different cause of Herford's mesothelioma: the aggressive radiation treatments she received for breast cancer in 1998. Therapeutic radiation is one of the only suspected causes of mesothelioma other than asbestos.

Following its victory, ***J&J blasted the “baseless theory” that its powders could be harmful. “Johnson’s Baby Powder has been around since 1894 and it does not contain asbestos or cause mesothelioma,”*** according to the company’s statement.

2. January 30, 2018 Disclosure

192. On January 30, testimony began in a new trial against J&J (the “Lanzo trial”), this time in New Jersey state court. The plaintiff, Stephen Lanzo, alleged that he developed mesothelioma on account of his exposure to Johnson’s Baby Powder containing asbestos. After the market had closed, *Law360* posted a story on the trial entitled, “No Asbestos In J&J Talc, NJ Jury Told in Mesothelioma Case.” The article stated in part:

The plaintiffs have asserted that Johnson & Johnson and an Imerys predecessor were aware that talc contained asbestos in the 1970s, around the time when Lanzo was born. For example, an attorney for the plaintiffs, Moshe Maimon of Levy Konigsberg LLP, on Monday cited a 1975 report in which the predecessor company allegedly said it found asbestos in the Johnson & Johnson powder.

Instead of warning the public about the asbestos or using corn starch instead of talc, ***Johnson & Johnson “got together with other companies that were selling talc and they chose to call the asbestos something else*** – I guess on the theory that if you don’t call it asbestos, then it can’t cause asbestos-related diseases,” Maimon told jurors in his opening statement.

193. In response to this disclosure, J&J's stock dropped 3% from a close of \$142.43 on January 30, 2018 to a close of \$138.19 on January 31, 2018. An event study has determined that this decline was statistically significant.

3. February 5, 2018 Disclosure

194. On February 5, 2018, Mesothelioma.net posted a story entitled "Johnson & Johnson Mesothelioma Trial Likely to Expose Company Documents" (the "Mesothelioma.net article"). Referring to the proceedings against J&J in New Jersey, the article reported that "experts are anticipating the release of numerous damaging internal company documents":

As a new mesothelioma lawsuit against Johnson & Johnson proceeds in a New Jersey courtroom, *experts are anticipating the release of numerous damaging internal company documents*. These memos and reports show that as long ago as the early 1970s, company officials were questioning each other about the impact of asbestos, and specifically about how much asbestos an infant might inhale if the company's baby powder contained a 1% concentration of the carcinogen. This type of documentation is likely to weigh heavily against the consumer products giant as they assert in court that their product has always been completely asbestos free.

195. As a result of this information, the Company's stock declined over 5%, from a close of \$137.68 on February 2, 2018 to a close of \$130.39 on February 5, 2018, the following trading day. An event study has determined that this decline was statistically significant.

196. Publications from news outlets and analysts illustrate that the stock drop was in response to the Mesothelioma.net article. For example, a February 5, 2018

CNBC article entitled “Johnson & Johnson falls on report that lawsuits could expose potentially damaging documents” (the “2018 CNBC article”) reported:

Shares of Johnson & Johnson fell Monday on a report that court proceedings could expose potentially damaging documents.

J&J is facing numerous lawsuits claiming its talc products such as Johnson’s Baby Powder caused cancer. The company has insisted its baby powder does not contain asbestos and causes neither mesothelioma nor ovarian cancer.

* * *

J&J’s stock fell 5 percent on Monday. Jefferies analyst Jared Holz said the report reads poorly, but he doubts it will have a real impact.

In a note to investors, Wells Fargo analyst Larry Biegelsen said the concerns on the talc lawsuits “appear overblown.”

Even if J&J settled all 5,500 cases for \$280,000 per case (the highest amount among liability cases in the drug and device sectors the firm has tracked), the total liability to J&J would be \$1.5 billion, he wrote. At the end of the fourth quarter, J&J had \$18.4 billion of cash and marketable securities.

197. And according to a February 5, 2018 post on benzinga.com, traders were circulating the Mesothelioma.net article, which caused the price to decline:

J&J Shares Fall 3.3%, Quickly Rebound From Lows But Still Down ~2.5% For Session; Traders Circulate Mesothelioma.net Article ‘Johnson & Johnson Mesothelioma Trial Likely to Expose Company Documents’

This headline-only article is meant to show you ***why a stock is moving***, the most difficult aspect of stock trading.

198. As referenced in the 2018 CNBC article, analysts at Wells Fargo reported that while the concerns “‘appear[ed] overblown,’” the drop in J&J stock was “partly

due to concerns about ongoing litigation over allegations that its talcum powder products are unsafe for use because they contain asbestos”:

JNJ: Talc Litigation Concerns Appear Overblown

- Summary. JNJ shares were down 5.3% on Feb 5 (vs 4.1% for the S&P 500) partly due to concerns about ongoing litigation over allegations that its talcum powder [sic] products are unsafe for use because they contain asbestos which can cause mesothelioma. JNJ issued a statement intraday defending the safety of its talc products noting that the products have been free of asbestos, based on decades of monitoring, testing and regulation dating back to the 1970s. According to JNJ, there are 5,500 talc cases nationwide and these include both ovarian cancer and mesothelioma claims. The only verdict in a mesothelioma case thus far was ruled in favor of JNJ. In addition, there have been a number of ovarian cancer cases which have been overturned in favor of JNJ. Based on prior high profile product liability cases in the drug and device sectors, we believe any potential settlement would be manageable for JNJ Even if all 5,500 talc cases settled for \$280,000 per case (the highest per case settlement amount among the cases we’ve tracked), the total liability to JNJ would be \$1.5B. At the end of Q4 2017, JNJ had \$18.4B of cash and marketable securities.

199. Finally, a February 2018 report by CrispIdea Research stated that “[c]urrently, JNJ has been facing a litigation on its baby powder product *which has led to the recent decline in its stock price*. It might result [in] further decline in stock performance and growth.” It also stated that “[d]ue to the recent downfall in stock prices and the litigations faced by the company, its P/E is now around the 18x band.”

200. To keep the full truth from being exposed and maintain inflation in the stock price, defendants continued to deny that J&J had any problem with its Baby

Powder and again falsely promised that its talc products “‘always have been’” asbestos free. The 2018 CNBC article quoted a J&J spokesman:

In a statement, a J&J spokesman pointed to a California judge ruling in favor of J&J in November in a lawsuit by a woman who said she developed mesothelioma after using the company’s talc-based products. He said the company would continue to defend its position in future cases.

“We are confident that our talc products are, and always have been, free of asbestos, based on decades of monitoring, testing and regulation dating back to the 1970s,” he said. “Historical testing of samples by the FDA, numerous independent laboratories, and numerous independent scientists have all confirmed the absence of asbestos in our talc products.”

4. February 7, 2018 Disclosure

201. On February 7, 2018, the Beasley Allen Law Firm published a press release entitled “New Johnson & Johnson, Imerys Documents Reveal More Cancer Links to Talc, Asbestos, Heavy Metals,” with the byline “Ovarian cancer victims demand answers amid growing findings from J&J trials”:

New information highlighting the links between talc, asbestos, heavy metals and cancer continue to surface as ovarian cancer victims use the legal system to press Johnson & Johnson for answers about the health risks of its popular talcum powder products, including Johnson’s Baby Powder and Shower To Shower.

Lawsuits filed by ovarian cancer and mesothelioma victims are revealing never-before-seen documents from Johnson & Johnson and talc supplier, Imerys, that shed light on just how prevalent asbestos and heavy metals are in the talc used in Baby Powder. The documents also show the corporations’ response to growing concerns about cancer risks.

“Over the last 90 days, we’ve seen a dramatic increase in document production from Johnson & Johnson and Imerys,” said

attorney Ted Meadows, principal at the Beasley Allen law firm and co-lead counsel in litigation on behalf of thousands of women diagnosed with ovarian cancer. “These documents are highly relevant to our claims that Johnson & Johnson and Imerys have known about these risks for a long, long time.”

Cancer victims suing J&J and Imerys argue that the corporations failed to provide warning labels on talc products despite knowing for decades about talc’s link to cancer. *Although numerous cases have already been tried, the corporate giants continue to reveal more hidden information, adding to a growing body of knowledge about the safety of talc products and their response.*

“Even though we’ve already gone to trial against these companies on numerous occasions, *they are just now getting around to turning over documents* that are proving to be very significant in these cases,” Mr. Meadows said.

202. In response, J&J’s stock declined nearly 4%, from a close of \$131.42 on February 7, 2018 to a close of \$126.36 on February 8, 2018. An event study has determined that this decline was statistically significant.

203. To hide the truth, maintain the stock price and protect the Company’s reputation at all costs, defendants again invoked the Company’s Credo and falsely claimed that defendants were living up to it. Indeed, on February 26, defendant Gorsky told investors that the Company’s Credo “formed . . . the strategy outline for Johnson & Johnson in everything we do.”

5. Defendants Continue to Mislead Investors, as J&J Relaunches Its Baby Product Line and Defendant Peterson Unexpectedly Retires

204. In April 2018, the jury in the Lanzo trial found J&J and its talc supplier liable for the plaintiff’s mesothelioma, ultimately awarding a total verdict of \$117

million. In response, J&J promised investors that the full evidence had not been reviewed. As reported by the *New York Daily News*:

J&J denied that its products contain cancer-causing toxins and says it plans to appeal.

“Johnson’s Baby Powder has been used for more than 120 years and it does not contain asbestos or cause mesothelioma,” said spokeswoman Carol Goodrich. ***“We believe that once the full evidence is reviewed, this decision will be reversed.”***

205. On April 26, 2018, defendant Gorsky again invoked the Company’s Credo at J&J’s Annual Shareholders Meeting, promising investors that “Our Credo” has “stood the test of time,” with J&J “liv[ing] into those responsibilities it outlines each and every day.” According to Gorsky, J&J “ha[d] continued to advance with the evolution of science and technology” and was “committed to meeting the needs” of “mothers and fathers and all others who use our products.” Boasting that J&J has “been focused on . . . health and well-being,” Gorsky promised that ***“we will always put the needs and well-being of the people we serve first.”*** In truth, Gorsky knew that J&J had not lived up to its Credo and was not putting “the needs and well-being” of people first. Nor had J&J advanced “with the evolution of science and technology,” as the Company never adopted concentration methods for testing its talc for asbestos despite knowing that this was required, while knowingly exposing consumers to a recognized carcinogen.

206. In a desperate attempt to preserve the reputation of its Baby Powder and itself, J&J announced in May 2018 that it was relaunching its iconic Johnson's Baby product line. On May 16, 2018, defendant Gorsky made himself available for an interview with CNBC, in which he boldly claimed that *J&J had "taken out many of the concerning . . . ingredients, that . . . mothers didn't want in their products,"* promising that "when it comes to babies, safety [and] high quality has got to be first and foremost in everything that we do." Gorsky also boasted of J&J's "clinical data and information," shared "with the broader community," showing that the Company's talcum powder is safe. In truth, Gorsky knew or recklessly disregarded that J&J's talc had long been contaminated with asbestos.

207. Also on May 16, 2018, defendants made numerous false and misleading statements to investors at the Consumer and Medical Devices Business Review. For example, Gorsky proclaimed that *"we're not afraid to acknowledge areas that we need to fix"* and professed J&J's desire "to talk about that [and] learn from them to make us better going forward." Indeed, despite the Company's longstanding campaign to cover up risks inherent in its talc products and its continued refusal to admit to its errors when it came to talc and asbestos, Gorsky promised that he and J&J had an "absolute commitment [to] hold ourselves accountable and . . . fulfill all of our Credo responsibilities where we always keep the customer and patients at the center of everything we do."

208. Meanwhile, at that same May 16, 2018 conference, Global Chief Technology Officer Josh Ghaim claimed that when it came to Johnson's Baby, "***our ingredients have . . . always been safe.***" Jorge Mesquita ("Mesquita"), Executive VP and Worldwide Chair of JJCI promised that "***we've been through this extensively, and we are 100% sure that our talc product is safe.***" Mesquita similarly promised on May 21, 2018 that "***[w]e are absolutely certain that science shows that our talcum product is safe.***"

209. At a May 21, 2018 conference, defendant Peterson represented that the Company's global supply chain had been largely fixed, and that she had ensured "***we've got the right quality and compliance in all of our manufacturing sites around the world, both internal and external.***" But Peterson knew or recklessly disregarded that the talc being supplied was improperly tested for asbestos, including that J&J never adopted a concentration method for its testing. Indeed, as the person brought in to fix quality issues at J&J, Peterson had access to the 2012 Audit Report of outside testing facility RJ Lee, which found numerous serious problems with the asbestos testing being done and noted that RJ Lee did not think J&J's testing method was "optimal."

210. On May 28, 2018 the *Wall Street Journal* reported J&J's promise that its talc product "***does not contain asbestos or cause mesothelioma.***" Once again, J&J relied on its defenses that it had carefully curated over the previous decades, as the

Wall Street Journal reported J&J's position that "over the past 50 years, multiple scientific evaluations, including from the [FDA], have been conducted and '***none have found that the talc in Johnson's Baby Powder contains asbestos.***'"

211. Then, on June 22, 2018, a little over two months after the first jury verdict against J&J in a case alleging harm from asbestos in the Company's talcum powders, J&J suddenly announced the retirement of corporate fixer defendant Peterson, effective October 1, 2018. Having been the first outsider ever to join J&J's executive committee, Peterson was leaving when her objective of fixing J&J's quality and supply chain issues was actually far from complete. And rather than have a replacement ready, J&J moved numerous executives around to make up for her departure.

212. The timing of Peterson's departure was particularly odd because she had taken on an additional management role a year prior, and had just presented at the J&J analyst meeting. A June 22, 2018 "Flash Comment" by Wells Fargo analysts expressed surprise over Peterson's abrupt exit:

The timing of the announcement was unexpected given her presentation at the JNJ analyst meeting in May and her relatively short tenure with the company. . . .

. . . Ms. Peterson joined JNJ a little over 5 years ago with responsibility for turning around Consumer, and improving the company's IT and supply chain. Her portfolio has grown since to include, among other things, leading the Hospital Medical Device business as of June 2017. Ms. Peterson's relatively short tenure at JNJ and even shorter tenure leading Medical Devices makes her departure a surprise to us.

6. July 12, 2018 Disclosure: J&J Is Hit with a \$4.69 Billion Talcum Powder Verdict but Claims It Was the Product of a Fundamentally Unfair Process and that J&J's Talc Is Safe

213. On July 12, 2018, J&J suffered its biggest loss to date in its defense of its “sacred cow” – a \$4.69 billion jury verdict against the Company, including \$4.14 billion in punitive damages in the Ingham trial. This was the first trial against J&J in which the plaintiffs alleged that their ovarian cancer was caused by asbestos in the talc, rather than by the talc itself.

214. As a result of this widely reported verdict, the Company's stock price declined over 1%. An event study has determined that this decline was statistically significant.

215. Market commentators and analysts recognized that the nearly \$5 billion verdict caused the stock price decline. In an article entitled “*J&J's \$4.69 Billion Talc Loss Hands Investors a What-Next Moment*,” Bloomberg reported:

Johnson & Johnson slipped as investors began to assess the potential long-term costs to the company of the legal saga surrounding its talc products.

On Thursday, a jury ordered the company to pay \$4.69 billion to women who claimed asbestos in the products caused them to develop ovarian cancer, marking *the sixth-largest product-defect verdict in U.S. history*.

The award – \$4.14 billion in punitive damages and \$550 million to compensate 22 women and their families – *was a drag on J&J shares*, which fell 0.7 percent to \$126.83 at 10:00 a.m. in New York, *even as major market indexes were little-changed*.

216. Numerous media outlets reported that J&J's stock price was affected by the jury's decision. For example, in an article entitled "Jury orders J&J to pay \$4.7 billion in Missouri asbestos cancer case," *Reuters* reported:

A Missouri jury on Thursday ordered Johnson & Johnson (JNJ.N) to pay a record \$4.69 billion to 22 women who alleged the company's talc-based products, including its baby powder, contain asbestos and caused them to develop ovarian cancer.

* * *

J&J shares fell \$1.31, or 1 percent, to \$126.45 in after-hours trading following the punitive damages award. They had risen \$1.52 during regular trading.

217. Other news outlets reported similarly. For example, a *Fast Company* article reported that "Johnson & Johnson's stock drops after ovarian cancer fight results in \$4.7B ruling." According to the report, "[a]lready, Johnson & Johnson is reeling from the decision; its stock is down nearly 3% in premarket trading." *Fortune* stated that J&J's "shares fell 1.9% following the ruling." And in a report entitled "Why Johnson & Johnson Was Down 2% This Morning," *Market Realist* reported that the Company's stock "was trading 2% lower during pre-market trading on news that the company must pay \$4.7 billion."

218. According to a report by *The Street*, J&J "shares tumbled Friday" after the jury verdict, as "Johnson & Johnson shares were marked 1.21% lower at the opening of trading in New York to change hands at \$126.22 each, a move that extends its year-to-date decline to 11%." Meanwhile, a July 13, 2018 report by *Barron's*

entitled “Updated: J&J Slumps on \$4.7 Billion Award to Cancer Patients” stated: “Shares of Johnson & Johnson (JNJ) are falling on Friday, on news that the company’s been ordered to pay a large fine related to claims that its baby powder caused cancer. . . . J&J is down 1.4% to \$125.85 this morning.”

219. Desperate to preserve public perception of the Company and its Baby Powder, J&J told investors that the verdict “was the product of a fundamentally unfair process.” In a July 12, 2018 corporate statement, J&J promised that “the evidence in the case was simply overwhelmed by the prejudice” J&J had suffered during the proceeding, and ***J&J “remains confident that its products do not contain asbestos and do not cause ovarian cancer.”*** Indeed, J&J effectively promised investors that the verdict would be reversed on appeal, representing that “the multiple errors in this trial were worse than those in the prior trials which have been reversed.”

220. Similarly, *Bloomberg* reported on July 12, 2018 that defendant Goodrich had stated in an email that the verdict ““was the product of a fundamentally unfair process,”” and that ““the evidence in the case was simply overwhelmed by the prejudice”” of the proceeding. Goodrich also blamed ““multiple errors”” in the proceeding for the verdict and again promised that J&J’s products were asbestos-free and did not cause ovarian cancer.

221. Then, on July 17, 2018, defendant Gorsky made numerous false and misleading statements to investors during the Company’s second quarter of 2018

(“2Q18”) Earnings Call. With investors concerned over the allegations and recent verdict surrounding J&J’s talcum powder, Gorsky promised that “we are always guided by our credo” and that “[o]ur credo is as relevant today as the day it was written,” with J&J “remain[ing] committed to fulfilling our credo responsibilities.” According to Gorsky, J&J was “inspired by our credo and we live in the responsibilities it outlines each and every day.” Gorsky addressed the Company’s attempt at “revitalizing our baby business,” promising that the products in that portfolio are “science-based and professionally endorsed products.” In truth, however, Gorsky knew that J&J had not acted in accordance with the Credo but rather had put the Company’s own reputation above the safety of consumers. While Gorsky promised the Company’s baby products were “science-based,” he knew or recklessly disregarded that Johnson’s Baby Powder contained asbestos – a recognized carcinogen.

222. During the July 17, 2018 call, Gorsky also addressed “the recent St. Louis talcum powder lawsuit and verdict” specifically. He assured investors that “*we remain confident that our products do not contain asbestos and do not cause ovarian cancer,*” and vowed to appeal the verdict. Gorsky further insisted that “*preeminent scientific and regulatory bodies . . . have fully reviewed the full body of scientific evidence on multiple occasions and found that it does not support the allegation that talc causes ovarian cancer.*” But as Gorsky knew or recklessly

disregarded, J&J had a long history of misleading scientific and regulatory bodies examining talc and concealing the dangers inherent in the Company's talcum powder.

7. December 14, 2018 Disclosure: *Reuters* Investigative Report Reveals New Information and Declares that “Johnson & Johnson Knew for Decades that Asbestos Lurked in Its Baby Powder”

223. On December 14, 2018, *Reuters* published a highly detailed investigative report entitled, “*Powder Keg: Johnson & Johnson knew for decades that asbestos lurked in its Baby Powder*” (the “*Reuters* report”) See Ex. 3. There, the well-respected news organization directly refuted defendants' false statements and provided never-before-seen internal J&J documents that detailed J&J's knowledge of the asbestos in the Company's talcum powder and J&J's longstanding fraudulent scheme to cover it up. The report disclosed new information and new analysis, including that:

A *Reuters* examination of many of those [J&J] documents, as well as deposition and trial testimony, shows that *from at least 1971 to the early 2000s, the company's raw talc and finished powders sometimes tested positive for small amounts of asbestos, and that company executives, mine managers, scientists, doctors and lawyers fretted over the problem and how to address it while failing to disclose it to regulators or the public.*

The documents also depict *successful efforts to influence U.S. regulators' plans to limit asbestos in cosmetic talc products and scientific research on the health effects of talc.*

A small portion of the documents have been produced at trial and cited in media reports. *Many were shielded from public view by court orders that allowed J&J to turn over thousands of documents it*

designated as confidential. Much of their contents is reported here for the first time.

224. Among the many details revealed by *Reuters*, the report provided investors with the full internal draft of J&J’s “Our Safety & Care Commitment” website, with the metadata showing that *defendant Goodrich had worked on the communication and even had the draft language in her files*. This document evidenced J&J’s internal recognition that the use of talc for over 100 years was not safe, as the copy for the website contained the following edit: “Talc has over 100 years of ~~safe~~ use in personal care products.” In addition, the copy for the website admitted that “*I don’t think we can link cosmetic talc to 100 years of use,*” and defendants J&J and Goodrich acknowledged internally what they had concealed from investors – that “*we cannot say ‘always’*” when it comes to asbestos not being in J&J’s talcum powder products.

225. The draft language also demonstrated defendants’ knowledge that the science on talc and ovarian cancer was not clearly in J&J’s favor, acknowledging that there were other scientific sources that were not included on the website because “they [were] not as definitive or supportive and *could be interpreted as suggesting a causal effect,*” including from such preeminent organizations as the American Cancer Society and IARC. *See* Ex. 2. Indeed, in the draft language for the website, a “NOTE TO CAROL/JAY” specifically informed defendant Goodrich that “*[e]ven some of the studies we cite send mixed messages.*” Goodrich was even informed that one of the

studies cited by J&J actually acknowledged that “*perineal talc use may modestly increase the risk of invasive serous ovarian cancers.*”

226. Contrary to defendants’ repeated assurances about the historical safety of talc, the *Reuters* report also provided new details of J&J’s early awareness of the dangers of tremolite in the Company’s talc:

[I]n an April 9, 1969, memo to a company doctor, *Ashton said it was “normal” to find tremolite in many U.S. talc deposits.* He suggested J&J rethink its approach. “Historically, in our Company, Tremolite has been bad,” Ashton wrote. “How bad is Tremolite medically, and how much of it can safely be in a talc base we might develop?”

Since pulmonary disease, including cancer, appeared to be on the rise, “it would seem to be prudent to limit any possible content of Tremolite . . . to an absolute minimum,” came the reply from another physician executive days later.

The doctor told Ashton that J&J was receiving safety questions from pediatricians. *Even Robert Wood Johnson II, the founder’s son and then-retired CEO, had expressed “concern over the possibility of the adverse effects on the lungs of babies or mothers,”* he wrote.

“We have replied,” the doctor wrote, that “we would not regard the usage of our powders as presenting any hazard.” *Such assurances would be impossible, he added, “if we do include Tremolite in more than unavoidable trace amounts.”*

The memo is the earliest J&J document reviewed by *Reuters* that discusses tremolite as more than a scratchy nuisance. *The doctor urged Ashton to consult with company lawyers because “it is not inconceivable that we could become involved in litigation.”*

227. The *Reuters* report also corrected defendants’ statements about early talc testing and J&J’s interaction with the FDA. Indeed, contrary to the September 21, 2017 *Bloomberg* article stating that “[d]ocuments provided by J&J show tests of its

talc stretching back to at least 1972 found no traces of asbestos,” the *Reuters* report disclosed that “at least three tests by three different labs from 1972 to 1975 had found asbestos in [J&J’s] talc – in one case at levels reported as ‘rather high’”:

In 1976, as the U.S. Food and Drug Administration (FDA) was weighing limits on asbestos in cosmetic talc products, ***J&J assured the regulator that no asbestos was “detected in any sample” of talc produced between December 1972 and October 1973. It didn’t tell the agency that at least three tests by three different labs from 1972 to 1975 had found asbestos in its talc – in one case at levels reported as “rather high.”***

228. The *Reuters* report also provided numerous other facts belying defendants’ fraudulent promises about J&J’s talc. Examples include:

- The July 1971 admission of J&J’s Wilson Nashed that the Company’s talc had “trace amounts of ‘fibrous minerals (tremolite/actinolite)’”;
- University of Minnesota Professor Thomas E. Hutchinson’s finding of “***incontrovertible asbestos***” in a Shower to Shower sample in 1972, which J&J failed to mention in a submission to the FDA;
- J&J’s creation of a list of “‘Antagonistic Personalities’” in 1972, which included Mount Sinai researcher Dr. Arthur Langer, who had told J&J in 1971 that his team had found “a ‘relatively small amount’ of chrysotile asbestos” in J&J’s talc, and who, according to *Reuters*, “said ***he told J&J lawyers who visited him last year [i.e., 2017] that he stood by all of his findings***”;
- J&J’s program in 1973 under the direction of Tom Shelley that was directed at finding a way to remove tremolite from talc and considered seeking patents on the processes, but eventually recognized that “***we may wish to keep the whole thing confidential rather than*** allow it to be published in patent form and thus ***let the whole world know***”;
- J&J October 1973 recognition that “our talc is acceptable” under a regulation proposed by FDA, but “***if they change the method, we may have problems***”;

- The 1992 Cyprus Minerals report stating that “Cyprus staff report past tremolite from the Hammondsville” deposit, which *Reuters* reported as having been “the primary source of Baby Powder talc from 1966 until its shutdown in 1990”;
- The 1993 J&J memorandum revealing that “records of the Hammondsville mine, the main source of Baby Powder talc from 1966 until 1990, were destroyed by mine managers while J&J still owned the business”;
- The 1998 letter to J&J’s legal counsel from Dr. Alice Blount, which confirmed that she had found “trace amounts of asbestos” in “Johnson & Johnson’s Vermont talc”;
- That “[i]n 2002 and 2003, Vermont mine operators found chrysotile asbestos fibers on several occasions in talc produced for Baby Powder sold in Canada. In each case, a single fiber was recorded – a finding deemed ‘BDL’ – below detection limit.”

229. And contrary to defendants’ many references to the FDA’s purported conclusion that talc is safe, *Reuters* reported that FDA Commissioner Scott Gottlieb “recognize[s] the concern” and “[h]e said the agency’s policing of cosmetics in general – fewer than 30 people regulating a ‘vast’ industry – was ‘a place where we think we can be doing more.’” Indeed, “Gottlieb said the FDA planned to host a public forum in early 2019 to ‘look at how we would develop standards for evaluating any potential risk.’”

230. In addition to these disclosures, *Reuters* reported that J&J had never adopted a concentration method for its asbestos testing, even after being informed that it was “[t]he best way to detect asbestos in talc,” and even after J&J’s own researchers used such a method to successfully identify asbestos in Vermont talc:

The best way to detect asbestos in talc was to concentrate the sample and then examine it through microscopes, the Colorado School of Mines Research Institute told J&J in a Dec. 27, 1973, report. In a [May 1973] memo, a J&J lab supervisor said *the concentration technique, which the company's own researchers had earlier used to identify a "tremolite-type" asbestos in Vermont talc*, had one limitation: *"It may be too sensitive."*

* * *

[T]he company never adopted the Colorado lab's 1973 recommendation that samples be concentrated before examination under a microscope. And the talc samples that were subjected to the most sensitive electron microscopy test were a tiny fraction of what was sold. For those and other reasons, J&J couldn't guarantee its Baby Powder was asbestos-free when plaintiffs used it, according to experts, including some who testified for plaintiffs.

As early as 1976, Ashton, J&J's longtime talc overseer, recognized as much in a memo to colleagues. He wrote that *talc in general, if subjected to the most sensitive testing method, using concentrated samples, "will be hard pressed in supporting purity claims."* He described this sort of testing as both *"sophisticated" and "disturbing."*

231. The *Reuters* report also revealed that J&J had purposely set out to manipulate scientists and regulators. Indeed, the report provided:

By 1977, J&J appeared to have tamped down concerns about the safety of talc. An internal August report on J&J's *"Defense of Talc Safety"* campaign noted that independent authorities had deemed cosmetic talc products to be "free of hazard." It *attributed "this growing opinion" to the dissemination to scientific and medical communities in the United States and Britain of "favorable data from the various J&J sponsored studies."*

232. And in a companion piece entitled "A guiding hand on talc safety research," *Reuters* reported on J&J's strategy for influencing scientific research,

including the March 1975 memorandum stating that J&J had been able “*to neutralize or hold in check data already generated by investigators who question the safety of talc.*” *Reuters* further reported:

J&J’s effort to protect its iconic Baby Powder franchise by shaping research was led by physician and scientist executives. An early 1970s study of 1,992 Italian talc miners shows how it worked: J&J commissioned and paid for the study, told the researchers the results it wanted, and hired a ghostwriter to redraft the article that presented the findings in a journal.

The effort entailed *other attempts to influence research*, including a U.S. government study of the health of talc workers in Vermont. J&J’s Windsor Minerals Inc. subsidiary, one of several mine operators involved in the study, developed a relationship with the U.S. National Institute of Occupational Safety and Health researchers to “*even influence the conclusions*” *through suggestions of “subjective interpretations,”* according to a 1973 Windsor Minerals memo.

233. In response to the *Reuters* report, J&J’s stock plummeted 10%, dropping from a closing price of \$147.84 the day before to a closing price of \$133.00. An event study has determined that this decline was statistically significant.

234. Financial analysts and market commentators recognized that the *Reuters* report revealed new information and caused the stock price decline. According to a CNBC article entitled “J&J shares plunge 10% after report that the company knew for decades about asbestos in baby powder,” the report by *Reuters* “*drove the company’s shares down more than 10 percent Friday.*” A second article by CNBC, entitled “*Johnson & Johnson loses \$39.8 billion in market value in one day* after report claims it knew about asbestos in its baby powder” reported:

Johnson & Johnson lost \$39.8 billion in market value Friday, suffering its worst trading day in more than 15 years, after Reuters said the company knew for decades that its baby powder contained asbestos – an allegation the company denied.

* * *

Friday's report spooked the Street and drove J&J's shares down 10.04 percent to close at \$133 a share, losing about \$39.8 billion of its market value.

235. On December 14, 2018, following the *Reuters* report, analysts at the Center for Financial Research and Analysis LLC ("CFRA") lowered their opinion on J&J from "buy" to "hold" and dropped their price target by \$30 per share. The CFRA analysts based this analysis on the new information and new analysis disclosed by the *Reuters* report and stated, "we expect a negative impact from recent allegations of cancer-causing asbestos in certain products." ***The CFRA report made clear that the new information and analysis revealed by Reuters would cause "significant damage" to J&J's "valuable brand name" because consumer trust is "critical" to J&J's success:***

Reporting surfaced today alleging JNJ did not disclose to the FDA that asbestos had sometimes been found in its baby powder ingredients dating back to the 1970s. JNJ vehemently denies this, but either way, we expect significant damage will unfold for JNJ's valuable brand name in consumer products and medical devices, which has been built over decades. The Consumer and Medical Devices segments generate 39% of profits, and the brand name and accompanying consumer trust are critical for their success. ***We see today's news potentially impacting sales of everything from baby shampoo to prosthetic hips. Given these elevated risks, we no longer feel JNJ shares are attractive at recent prices.***

236. Financial analysts at UBS and Wells Fargo also recognized that the *Reuters* report caused the stock price decline. On December 14, 2018, Wells Fargo stated that “JNJ shares are down ~10% (vs -1% for the S&P 500) this morning, following a Reuters article that suggests the company knew about asbestos in its baby powder for decades but never told the FDA.” And, that same day, UBS analysts stated:

JNJ shares are down ~10% after Reuters published an article this morning . . . stating that internal JNJ company documents showed that its baby talc powder had historically tested positive for low levels of asbestos on a number of occasions and that the company concealed this information from the FDA in 1970s.

237. Other analysts also explicitly recognized that the *Reuters* report disclosed new information – including internal Company documents, “***reported to the public for the first time.***” For example, on December 14, 2018, Credit Suisse analysts stated that they had spoken with J&J investor relations executives that day and J&J stated that the Company’s litigation risk was purportedly unchanged by the *Reuters* revelations because, “[w]hile the documents that the Reuters article cited may be reported to the public for the first time,” the internal Company documents, “have been used in previous court cases.”²³ Similarly assessing J&J’s litigation risk, on December 14,

²³ Credit Suisse also noted that according to J&J investor relations executives, the Company had “communicated with the author for weeks prior to the publication of the Reuters article.”

2018, financial analysts at Leerink noted that: “***documents cited in the article had not been previously shared with the public.***”

238. A December 21, 2018 report by *Bloomberg* entitled “J&J’s Tainted-Talc Risk Expands as Cancer Trials Triple in 2019” illustrated the dire situation for J&J going forward:

Johnson & Johnson paid a steep price this year for claims that its celebrated baby powder was contaminated with asbestos. Problem is, 2019 could be even worse.

A jury ordered the company in July to pay \$4.69 billion to 22 women who blamed the talc-based product for causing their ovarian cancer. ***The prospect of similar judgments helped erase \$45 billion in J&J’s market value***, with the shares headed for their biggest annual loss in a decade.

* * *

Investor concern over litigation risk has grown following media reports of internal documents showing company officials have known since the 1970s that some of the talc used in baby powder contained asbestos.

239. A January 12, 2019 *Seeking Alpha* article recognized that the damage from the *Reuters* report threatened to reach far beyond J&J’s Baby Products, stating that “J&J needs to guard against ‘reputational contagion,’ the risk that loss of confidence in Baby Powder could bleed over into how consumers, shareholders and others view the company more broadly.” In an effort to do damage control and support the Company’s stock price, J&J published full-page newspaper ads defending itself, announced a \$5 Billion stock buyback, and made a video regarding talc

featuring defendant Gorsky. In addition, Gorsky appeared on CNBC's "Mad Money" program, where he continued to deny asbestos contamination in the Company's talc.

240. Still, J&J could no longer conceal its failure to live up to its storied Credo and financial analysts linked the *Reuters* report's revelations to J&J's Credo statements. For example, as explained in the January 12, 2019 *Seeking Alpha* article:

[T]he documented asbestos contamination of J&J talc that Reuters investigated had occurred over a lengthy period of time and involved counter-credo J&J decisions, making it difficult to imagine J&J was not aware of any issues at some point. It also makes the effort at absolving itself unseemly.

Some of J&J's messages in its recent campaign to combat the talc issue actually omit key details regarding findings on talc and, in certain instances, are undermined by other evidence, according to a Reuters review of the company's statements.

241. And on January 25, 2019, a CFRA report provided further rationale for CFRA's lowered opinion of J&J and highlighted the importance of Baby Powder to J&J's overall reputation:

Brand-name reputation is critically important for the success of the Consumer segment, in our view. JNJ's Consumer products often face several low-price competing products. The trust in a brand name can make a big difference in sales, especially when it comes to health care products that one puts in or on their body or a loved one's body.

Due to the importance of brand power and consumer trust, we think allegations from a Reuters story published in December 2018 could have a meaningful negative impact on JNJ's Consumer segment, as well as the Medical Devices segment to a lesser extent. The report alleges that JNJ did not disclose to the FDA that asbestos had sometimes been found in its baby powder dating back to the 1970s. JNJ vehemently denies the allegations and is defending itself in court in related cases, as well as putting forth a major public relations campaign

to defend the safety of its baby powder and other products. Regardless, ***we think more reporting is likely to come out over the next year on this subject.*** And whether the reports have merit or not, we think ***there is a material risk that the more the issue is in the news, the less trust consumers will have in JNJ's brands.***

242. The new information revealed by the *Reuters* report directly refuted defendants' repeated denials, as well as defendants' continued insistence that science was on J&J's side. As a February 14, 2018 *Seeking Alpha* article noted, the *Reuters* report "revealed that JNJ executives were aware of the presence of asbestos in the company's raw and finished talc powders & attempted to conceal the findings from the public." The *Seeking Alpha* article further explained how J&J was able to hide the truth from investors until the *Reuters* report revelations:

The happy-go-lucky attitude of JNJ longs regarding the ongoing talcum powder/asbestos lawsuits was an understandable phenomenon. Scientific findings showed a tenuous connection between talc and asbestos with conflicting data, a perfect recipe for long incredulity. Reuters journalists left very little room for skepticism, however, following the special report published in December.

* * *

Documents highlighted in the Reuters report show that JNJ executives were not only aware of numerous internal and external reports of asbestos in JNJ talc powders, but actively stifled the findings without remedy.

243. And, a February 20, 2019 *Reuters* article also described the impact that the new information and new analysis in the December 14 *Reuters* report had on J&J's stock price:

A Reuters report on Dec. 14 revealed that Johnson & Johnson knew for decades that small amounts of asbestos, a known carcinogen, had been occasionally found in its talc and powder products, according to tests from the 1970s to the early 2000s – information it did not disclose to regulators or the public.

The Reuters article prompted a selloff in Johnson & Johnson shares, erasing about \$40 billion from the company's market value in one day, and a public relations crisis as the healthcare conglomerate faced widespread questions about the possible health effects of one of its most iconic products.

K. The Aftermath

244. By publicly revealing new details and new analysis of J&J's longstanding knowledge of asbestos in its baby powder and talc, the *Reuters* report has created a crisis for J&J.

245. For example, on December 14, 2018, U.S. Senator Ed Markey, a member of the Environment and Public Works Committee, requested that the FDA "immediately investigate these allegations and determine whether Johnson & Johnson's actions have placed at risk the public's health and safety."

246. On December 19, 2018, J&J's motion to overturn the \$4.69 Billion verdict in the Ingham case was denied. According to an article by *Bloomberg* entitled "J&J Shares Fall After Judge Refuses to Overturn Talc Verdict," J&J stock "fell as much as 2.3 percent after a judge refused to throw out a \$4.69 billion verdict finding the company's baby powder is tainted with cancer-causing asbestos."

247. A *Law360* article outlines the rationale behind the Missouri judge's decision:

“First, substantial evidence was adduced at trial of *particularly reprehensible conduct on the part of defendants*, including that *defendants knew of the presence of asbestos in products that they knowingly targeted for sale to mothers and babies, knew of the damage their products caused and misrepresented the safety of these products for decades*,” the judge said. “Second, defendants’ actions caused significant physical harm and potential harm, including ovarian cancer in plaintiffs or plaintiffs’ decedents.”

248. And on January 28, 2019, U.S. Senator Patty Murray, Ranking Member of the Committee on Health, Education, Labor, and Pensions, sent defendant Gorsky a letter requesting documents related to the ““alleged decades-long effort by Johnson & Johnson to potentially mislead regulators and consumers about the safety”” of Baby Powder, as revealed by the *Reuters* report.

249. By February 13, 2019, J&J’s talc supplier, Imerys, filed for Chapter 11 bankruptcy protection. According to a *Bloomberg* article entitled, “Imerys Talc Units File Bankruptcy as Cancer-Suit Risk Soars,” “J&J shares fell as much as 0.7 percent on the bankruptcy filing,” and “[t]he bankruptcy will probably have a negative impact on Johnson & Johnson in thousands of talc lawsuits as Imerys won’t be able to contribute much capital to potential settlements.”

250. And, on February 20, 2019, J&J disclosed in its 2018 Form 10-K that the Company had received “preliminary inquiries and subpoenas” from Senator Patty Murray, the DOJ, and the SEC to produce documents regarding this securities class action lawsuit, as well as a shareholder derivative suit, two Employee Retirement

Income Security Act of 1974 class action lawsuits, and the product liability multidistrict litigation.

251. According to the *Wall Street Journal*, “[a] J&J spokesman said the inquiries were related to news reports in December about product-liability lawsuits against the company, which caused J&J’s stock price to fall sharply.” The *Wall Street Journal* also acknowledged that Johnson’s Baby Powder “plays an important role shaping J&J’s reputation” and that “[t]he talc-powder litigation threatens J&J’s carefully cultivated image.”

252. In response to the disclosure of the SEC and DOJ subpoenas, J&J’s stock price suffered further decline.

VI. DEFENDANTS’ MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS

A. February 2013 False and Misleading Statements

253. On February 22, 2013, J&J filed its Form 10-K with the SEC for the fiscal year ended December 30, 2012 (“2012 10-K”), which was signed by defendants Gorsky and Caruso. According to defendants, J&J “remain[ed]” committed” to “delivering high quality” and “improving existing products”:

Research and Development

Research activities represent a significant part of the Company’s businesses. Research and development expenditures relate to the processes of discovering, testing and developing new products, *improving existing products*, as well as demonstrating product efficacy and regulatory compliance prior to launch. *The Company remains*

committed to investing in research and development with the aim of delivering high quality and innovative products.

254. Exhibit 13 to the 2012 10-K disclosed that some of J&J's subsidiaries were involved in product liability litigation, but also represented that the warnings and instructions accompanying their products were adequate:

Certain subsidiaries of Johnson & Johnson are involved in numerous product liability cases. The damages claimed are substantial, and while *these subsidiaries are confident of the adequacy of the warnings and instructions for use that accompany the products at issue*, it is not feasible to predict the ultimate outcome of litigation. The Company has established product liability accruals in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. Changes to the accruals may be required in the future as additional information becomes available.

255. J&J's statements, as alleged in ¶¶253-254, were false and misleading when made. While defendants boasted of "improving existing products," being "committed to investing in research and development with the aim of delivering high quality . . . products," and having "adequate" warnings, they omitted that (i) asbestos had repeatedly been found in the Company's talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), and (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67, 230).

B. April 2013 False and Misleading Statements

256. On April 25, 2013, *Forbes* reported on comments made by J&J's VP of global corporate affairs, Michael Sneed, at J&J's annual shareholder meeting:

“One of the things that we wanted to be sure to do is move to *really get past some of the challenges we’ve had as a business*,” said Michael Sneed, VP of global corporate affairs. “*We’ve made great strides in that and we want to make sure we have a full conversation about who J&J is*. We’re not perfect but we want people to understand that *when we do make mistakes, we own up to those mistakes* and *we want people to understand the values that are behind J&J*.”

J&J ranked No. 6 of America’s 150 most reputable companies this year, dropping from No. 3 last year, according to The Reputation Institute.

“We certainly are not oblivious to the rankings,” Sneed said. “The reputation of J&J is very important to us. We take it very seriously. We have a lot of data that we look at, both externally and internally,” he said. “I wouldn’t say there was any one thing that precipitated [the campaign], and we certainly don’t do these things just for rankings. Reputation is something that’s born out of actions. The reputation is a reflection of people’s perspective on the actions that we do take.”

The corporate campaign is the first global one, will continue indefinitely and will cost an estimated \$20 million to \$30 million for the remainder of the year.

It comes at a time when many businesses such as Nestle, Unilever UN +0% and Procter & Gamble PG +1.22% recognize the value of corporate branding in an increasingly transparent and accessible world driven by social media. “*We’ve really embraced transparency* because we think we’ve got a great story to tell,” Sneed said. “It has made us even more committed to making sure that we’re part of the conversation wherever that conversation happens. Clearly, more of that conversation happens online and in the digital space. We love that things happen in real time. We get jazzed at being part of that,” he said, adding that employees, particularly the younger ones, are excited by the company’s involvement in social media, and “have become ambassadors for the brand.”

Sneed also pointed out that J&J has a history of doing corporate campaigns – for example, the Campaign for Nursing’s Future, which has been running for 10 years.

“As we were thinking about what else we wanted to do, we thought it was important to reconnect with customers, healthcare professionals, and reconnect them to J&J and *really [help them] understand the values behind J&J*. The campaign is about celebrating the people who do the work of caring for others and in a selfless manner.”

The central theme of the new ads, the first from TBWA LA, is *love* – “*an expression of what people do when they care unconditionally for others*,” Sneed said. “*That comes out of the history of J&J*.”

257. Defendants’ statements, as alleged in ¶256, that J&J had “‘really embraced transparency’” and was trying to “‘have a full conversation about who J&J is’” to help customers, healthcare professionals, and others “‘understand the values behind J&J,’” that J&J had a history of and was driven by “‘car[ing] unconditionally for others’” and that it had “‘own[ed] up to [its] mistakes,’” and that J&J made “‘great strides’” in “‘really get[ting] past’” the quality issues the Company faced, were false and misleading. In truth, defendants were continuing the longstanding campaign to conceal the dangers inherent in the Company’s talcum powders. Indeed, defendants failed to disclose that (i) asbestos had repeatedly been found in the Company’s talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67, 230), and (iv) J&J had purposely influenced and manipulated regulators and scientists in

order to protect the Company's flagship product and reputation (¶¶61- 62, 68-72, 78, 80, 82-86, 93-104, 223, 227, 231-232).

C. May 2013 False and Misleading Statements

258. On May 3, 2013, J&J filed its Form 10-Q with the SEC for the first quarter of 2013 ("1Q13 10-Q"). According to defendants, J&J "remain[ed] committed" to "delivering high quality" and "improving existing products":

Research and Development Expense

Research and development activities represent a significant part of the Company's business. These expenditures relate to the processes of discovering, testing and developing new products, *improving existing products*, as well as ensuring product efficacy and regulatory compliance prior to launch. *The Company remains committed to investing in research and development with the aim of delivering high quality and innovative products.*

259. J&J's 1Q13 10-Q disclosed that some of J&J's subsidiaries were involved in product liability litigation, but also represented that the warnings and instructions accompanying their products were adequate:

Certain subsidiaries of Johnson & Johnson are involved in numerous product liability cases. The damages claimed are substantial, and while *these subsidiaries are confident of the adequacy of the warnings and instructions for use that accompany the products at issue*, it is not feasible to predict the ultimate outcome of litigation. The Company has established product liability accruals in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. Changes to the accruals may be required in the future as additional information becomes available.

260. Defendants' statements, as alleged in ¶¶258-259, were false and misleading. While defendants boasted of "improving existing products," being

“committed to investing in research and development with the aim of delivering high quality . . . products,” and having “adequate” warnings, they omitted that (i) asbestos had repeatedly been found in the Company’s talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), and (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67, 230).

D. July 2013 False and Misleading Statements

261. During a July 16, 2013 conference call regarding the Company’s 2Q13 results, J&J provided more assurance to investors that J&J paid careful attention to the safety of its products and that as part of a “quality initiative,” the Company was identifying problems early and was correcting them:

[Sandy Peterson, Group Worldwide Chairman:] [O]ur quality effort is across the enterprise, across all of our businesses, our manufacturing sites as well as all of our R&D sites, because they are under the scope of ***trying to ensure that we have the highest standard of quality for the safety and care of our patients and consumers***. So, when we launched the quality initiative a number of years ago, the focus really was on ensuring that we’ve got consistent quality standards. . . .

. . . And we have, obviously as we’ve gone through all of this work, ***we have identified corrective actions, and we’ve immediately taken those corrective actions***. . . . We’re putting in place processes and systems so that ***we have early warning systems in place to understand if we think there may be something going on with a product. So we identify it early and we go out and correct it***.

In addition to that, an important component of all of this is how we’re managing our global supply chain. So, one of the very important changes that we have been making with our global supply chain is

ensuring that all of our external suppliers – so, our material suppliers – are thoroughly reviewed, are thoroughly managed, and that they are living up to our quality standards. And in that process in the last three years we’ve actually consolidated our external manufacturing, our external material suppliers by about one-third. So we have one-third less than we had three years ago. That means that we have an ability to manage them much more effectively, and ensure that we are reviewing their quality of their products coming into our facilities.

262. Defendants’ statements, as alleged in ¶261, that J&J was “trying to ensure . . . the highest standard of quality for . . . safety” identifying problems early and correcting them “immediately,” and “ensuring that [its] . . . external suppliers [were] living up to [J&J’s] quality standards” were false and misleading. In truth, defendants were continuing the Company’s campaign to conceal the dangers inherent in its talcum powders. Indeed, Peterson failed to disclose that (i) asbestos had repeatedly been found in the Company’s talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67, 230), and (iv) J&J had purposely influenced and manipulated regulators and scientists in order to protect the Company’s flagship product and reputation (¶¶61-62, 68-72, 78, 80, 82-86, 93-104, 223, 227, 231-232).

E. August to November 2013 False and Misleading Statements

263. On August 1, 2013, J&J filed its 2Q13 Form 10-Q with the SEC. According to defendants, J&J “remain[ed] committed” to “delivering high quality” and “improving existing products”:

Research and Development Expense

Research and development activities represent a significant part of the Company's business. These expenditures relate to the processes of discovering, testing and developing new products, ***improving existing products***, as well as ensuring product efficacy and regulatory compliance prior to launch. ***The Company remains committed to investing in research and development with the aim of delivering high quality and innovative products.***²⁴

264. J&J's 2Q13 10-Q disclosed that some of J&J's subsidiaries were involved in product liability litigation, but also represented that the warnings and instructions accompanying their products were adequate:

Certain subsidiaries of Johnson & Johnson are involved in numerous product liability cases. The damages claimed are substantial, and while ***these subsidiaries are confident of the adequacy of the warnings and instructions for use that accompany the products at issue***, it is not feasible to predict the ultimate outcome of litigation. The Company has established product liability accruals in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. Changes to the accruals may be required in the future as additional information becomes available.²⁵

265. Defendants' statements, as alleged in ¶¶263-264, were false and misleading. While defendants boasted of "improving existing products," being "committed to investing in research and development with the aim of delivering high quality. . . products," and having "adequate" warnings, they omitted that (i) asbestos

²⁴ These statements were also made in J&J's third quarter of 2013 ("3Q13") Form 10-Q, filed November 4, 2013.

²⁵ These statements were also made in J&J's 3Q13 Form 10-Q, filed November 4, 2013.

had repeatedly been found in the Company's talc and powders (§§55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (§§58, 60, 228), and (iii) J&J never adopted concentration methods that could detect the asbestos (§§63-67, 230).

F. January 2014 False and Misleading Statements

266. By January 7, 2014, J&J's "Our Safety & Care Commitment" website stated the following²⁶:

Few ingredients have demonstrated the same performance, mildness and safety profile as cosmetic talc, which has been used for over 100 years by millions of people around the world. Talcum powder is made from the mineral, talc. In a powder form, talc helps reduce friction, making it useful for keeping skin dry and helping to prevent rashes. Talc is a common natural ingredient found in cosmetic products such as baby powder and adult body and facial powders, and in a range of other consumer products such as toothpaste, chewing gum, and aspirin.

JOHNSON'S® Baby talc products are made using U.S. Pharmacopeial (USP) grade talc to *ensure it meets the highest-quality, purity and compliance standards. Our talc is carefully selected, processed and tested to ensure that [it] is asbestos free, as confirmed by regular testing conducted since the 1970s.*

* * *

At the Johnson & Johnson Family of Consumer Companies, *our confidence in using talc is based on a long history of safe use and more than 30 years of research by independent researchers, scientific review boards and global regulatory authorities. Various agencies and governmental bodies have examined whether talc is a carcinogen, and*

²⁶ Our Safety & Care Commitment, Johnson & Johnson Family of Consumer Companies, <http://www.safetyandcarecommitment.com:80/ingredient-info/other/Talc>.

none have concluded that it is. These include the U.S. Food and Drug Administration (FDA) and National Toxicology Program, part of the U.S. Department of Health and Human Services.

* * *

Many research papers and epidemiology studies have been published since the early 1990s studying talc and perineal use and *these studies have found talc to be safe*. A detailed *meta-analysis done by Muscat in 2007*, reviewed all available data and showed no cause and effect relationship between perineal use and ovarian cancer.²⁷

267. Defendants’ statements, as alleged in ¶266, were false and misleading. As alleged in ¶¶128 and 224, defendants J&J and Goodrich knew that talc did not have “a long history of safe use” after being “used for over 100 years,” as the draft language for the website in Goodrich’s possession illustrated that the 100 years of use was not safe and even noted that “I don’t think we can link cosmetic talc to 100 years of use.” And while the website boasts of talc’s “long history of safe use,” creating the impression that J&J’s talc has always been asbestos-free, as alleged in ¶¶128 and 224, Goodrich’s own draft admits that “we cannot say ‘always.’” In addition, these statements, as well as the representations regarding talc’s “safety profile” and “purity,” the representation that “[o]ur talc is carefully selected, processed and tested to ensure that [it] is asbestos free,” and the representation that “regular testing conducted since the 1970s” confirmed that J&J’s talc was asbestos free, were false

²⁷ Citing Muscat, *Perineal talc use and ovarian cancer risk: a case study of scientific standards in environmental epidemiology*, Eur. J. of Cancer Prevention, Nov. 11, 2011, <http://www.ncbi.nlm.nih.gov/pubmed/21712717>.

and misleading as they omitted that (i) asbestos had repeatedly been found in the Company's talc and powders(¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), and (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67, 230).

268. Defendants' representations, as alleged in ¶266, that "more than 30 years of research by independent researchers, scientific review boards and global regulatory authorities" supported the safety of talc, that studies "since the early 1990s . . . have found talc to be safe," and that "none" of the "[v]arious agencies and governmental bodies" have concluded that talc is a carcinogen, were false and misleading. As alleged in ¶¶131 and 225, J&J acknowledged internally that other scientific sources not included on the website were actually "not as definitive or supportive and could be interpreted as suggesting a causal effect" and that "[e]ven some of the studies we cite send mixed messages." And as alleged in ¶¶131 and 225, J&J knew that one of the studies cited by J&J even admitted that "'perineal talc use may modestly increase the risk of invasive serous ovarian cancers.'" In addition, the statements omitted that (i) asbestos had repeatedly been found in the Company's talc and powders, (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67, 230), and (iv) J&J had purposely influenced

and manipulated regulators and scientists, including the FDA and NTP, in order to protect the Company's flagship product and reputation (¶¶61-62, 68-72, 78, 80, 82-86, 93-104, 223, 227, 231-232).

269. On a January 21, 2014 conference call discussing J&J's 4Q13 and FY13 results, defendant Gorsky told investors that J&J's Chief Medical and Chief Quality Officers were "setting new benchmarks for medical safety" and were ensuring the Company's products were safe:

Our Chief Medical and Chief Quality Officers are setting new benchmarks for medical safety and implementing a more consistent global approach for monitoring the use of our end market products that is very patient- and consumer-centric for ensuring that they are safe and performing as expected and as intended. While we're pleased with the progress that we've made here, we're not yet satisfied and we'll keep doing whatever it takes to ensure that we continue to earn the trust of consumers and patients around the world.

270. Defendants' statements, as alleged in ¶269, that J&J had done and would continue to do "whatever it takes to ensure . . . the trust of consumers and patients," including "setting new benchmarks for medical safety" and "ensuring that the Company's products "are safe," were false and misleading. In truth, defendants were continuing the longstanding campaign to conceal the dangers inherent in the Company's talcum powders. Indeed, defendants failed to disclose that (i) asbestos had repeatedly been found in the Company's talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), (iii) J&J never adopted concentration methods that could

detect the asbestos (§§63-67, 230), and(iv) J&J had purposely influenced and manipulated regulators and scientists in order to protect the Company’s flagship product and reputation (§§61-62, 68-72, 78, 80, 82-86, 93-104, 223, 227, 231-232).

G. February to October 2014 False and Misleading Statements

271. On February 21, 2014, J&J filed its 2013 10-K with the SEC. Signed by defendants Gorsky and Caruso, the 2013 10-K again represented that J&J “remain[ed]” committed” to “delivering high quality” and “improving existing products”:

Research and Development

Research and Development activities represent a significant part of the Company’s business. [Research and development] expenditures relate to the processes of discovering, testing and developing new products, *improving existing products*, as well as ensuring product efficacy and regulatory compliance prior to launch. *The Company remains committed to investing in research and development with the aim of delivering high quality* and innovative products.

272. Exhibit 13 to the 2013 10-K disclosed that some of its subsidiaries were involved in product liability litigation, but also represented that the subsidiaries had “substantial defenses”:

Certain subsidiaries of Johnson & Johnson are involved in numerous product liability claims and lawsuits involving multiple products. Claimants in these cases seek substantial compensatory and, where available, punitive damages. While *these subsidiaries believe they have substantial defenses*, it is not feasible to predict the ultimate outcome of litigation. The Company has established product liability accruals in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. Changes to the

accruals may be required in the future as additional information becomes available.

273. On May 2, 2014, J&J filed its first quarter of 2014 (“1Q14”) Form 10-Q with the SEC. According to defendants, J&J “remain[ed]” committed” to “delivering high quality” and “improving existing products”:

Research and Development Expense

Research and development activities represent a significant part of the Company’s business. These expenditures relate to the processes of discovering, testing and developing new products, *improving existing products*, as well as ensuring product efficacy and regulatory compliance prior to launch. *The Company remains committed to investing in research and development with the aim of delivering high quality and innovative products.*

274. J&J’s 1Q14 10-Q disclosed that some of J&J’s subsidiaries were involved in product liability litigation, but also represented that the subsidiaries had “substantial defenses”:

Certain subsidiaries of Johnson & Johnson are involved in numerous product liability claims and lawsuits involving multiple products. Claimants in these cases seek substantial compensatory and, where available, punitive damages. While *these subsidiaries believe they have substantial defenses*, it is not feasible to predict the ultimate outcome of litigation. The Company has established product liability accruals in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. Changes to the accruals may be required in the future as additional information becomes available.²⁸

²⁸ These statements were also made in J&J’s 2Q14 and third quarter of 2014 (“3Q14”) Form 10-Qs (filed August 1, 2014 and October 30, 2014, respectively).

275. On August 1, 2014, J&J filed its second quarter of 2014 (“2Q14”) Form 10-Q with the SEC. According to defendants, J&J “remain[ed]” committed” to “delivering high quality”:

Research and Development Expense

The Company remains committed to investing in research and development with the aim of delivering high quality and innovative products.

276. Defendants’ statements, as alleged in ¶¶271-275, were false and misleading. While defendants boasted of “improving existing products,” being “committed to investing in research and development with the aim of delivering high quality . . . products,” and of J&J’s subsidiaries having “substantial defenses,” they omitted that (i) asbestos had repeatedly been found in the Company’s talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67, 230), and (iv) J&J had purposely influenced and manipulated regulators and scientists in order to protect the Company’s flagship product and reputation (¶¶61-62, 68-72, 78, 80, 82-86, 93-104, 223, 227, 231-232).

H. January to February 2015 False and Misleading Statements

277. During a JPMorgan Healthcare Conference on January 12, 2015, defendant Gorsky stated:

Quality and safety, our number-one priority in dealing with patients and consumers. We've made a number of changes over the last few years, frankly to ***make sure that we addressed any of the outstanding issues that we were facing***, but also more importantly to set us up for a benchmark going forward.

278. On February 5, 2015, defendant Glasgow created a page on J&J's website entitled "Making Every Moment Matter." She represented that J&J understood and cared about the needs of babies and that J&J "look[ed] at all the science" "that help our babies thrive and grow":

As a mom, I understand the need for other moms and dads to treasure the precious moments throughout the day we get to spend with our children. From bath time to bedtime, all of these moments turn into our very own special rituals and serve as a way to bond and develop a relationship with our little ones. What may come as a surprise to some is how all of these everyday interactions serve as the perfect opportunity to stimulate your baby's senses, which we believe can have a positive impact on their development.

Working on JOHNSON'S®, I've had the chance to meet parents all over the world and look at the unique rituals and practices between them and their baby. What I found to be universal is the desire for families to raise happy, healthy babies.

As the first baby care brand to commit to advancing the science of baby's skin, we feel, as scientists, an obligation to continue to take our research to the next level by looking at all the science – even beyond the science focused on cleansing – that help our babies thrive and grow. It's why I am so excited about the new and existing research we are sharing that reveals the importance of multi-sensorial experiences that can lead to happy, healthy baby development.

By age three, 85% of a baby's brain is developed so it's no surprise that every experience leading up to this time helps to shape their brain. From the nighttime cuddles to the bath time bubble splashing sessions, all of these interactions are giving you ***an opportunity to nurture your baby's ability to learn***, think, love and grow. And even

more interesting is how the brain's processes for learning are enhanced when multiple senses are stimulated versus just using one. It's why *I spend a lot of time looking at how touch and smell work together so we can help families make the little moments – like bath time (and what I like to call a sensorial playground) – mean so much more.*

Looking into the future, JOHNSON'S® has earmarked millions of dollars over the next three years to advance new research and will continue to partner with leading experts in the space to uncover even more about the "science of the senses."

279. Defendants' statements, as alleged in ¶277, that "[q]uality and safety [were J&J's] number-one priority" and that J&J had "addressed any of the outstanding issues that [it was] facing," were false and misleading. In truth, J&J continued its longstanding fraudulent scheme to protect the image of Baby Powder's safety and the Company's reputation, concealing that (i) asbestos had repeatedly been found in the Company's talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67, 230), and (iv) J&J had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation (¶¶61-62, 68-72, 78, 80, 82-86, 93-104, 223, 227, 231-232).

280. Defendants' statements, as alleged in ¶278, that J&J "continue[d] to take [its] research to the next level by looking at all the science . . . that help our babies thrive and grow" and that J&J "help[ed] families make the little moments – like bath time" serve as "an opportunity to nurture your baby's ability to learn," were similarly

false and misleading. Instead of “looking at all the science” or helping families nurture their babies, J&J had provided parents with the opportunity to unwittingly expose their children to asbestos, while the Company continued to reject appropriate testing methods and ignored the multiple findings of asbestos in its talc powders. Defendants concealed that (i) asbestos had repeatedly been found in the Company’s talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67, 230), and (iv) J&J had purposely influenced and manipulated regulators and scientists in order to protect the Company’s flagship product and reputation (¶¶61-62, 68-72, 78, 80, 82-86, 93-104, 223, 227, 231-232).

281. On February 24, 2015, J&J filed its 2014 10-K with the SEC (“2014 10-K”). Signed by defendants Gorsky and Caruso, the 2014 10-K again represented that J&J “remain[ed]” committed” to “delivering high quality” and “improving existing products”:

Research and Development

Research activities represent a significant part of the Company’s businesses. Research and development expenditures relate to the processes of discovering, testing and developing new products, *improving existing products*, as well as demonstrating product efficacy and regulatory compliance prior to launch. *The Company remains committed to investing in research and development with the aim of delivering high quality* and innovative products.

282. Exhibit 13 to the 2014 10-K disclosed that some of its subsidiaries were involved in product liability litigation, but also represented that the subsidiaries “have substantial defenses”:

Certain subsidiaries of Johnson & Johnson are involved in numerous product liability claims and lawsuits involving multiple products. Claimants in these cases seek substantial compensatory and, where available, punitive damages. While *these subsidiaries believe they have substantial defenses*, it is not feasible to predict the ultimate outcome of litigation. The Company has established product liability accruals in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. In addition, product liability accruals can represent projected product liability for thousands of claims around the world, each in different litigation environments and with different fact patterns. Changes to the accruals may be required in the future as additional information becomes available.

283. Defendants’ statements, as alleged in ¶¶281-282, were false and misleading. While defendants boasted of “improving existing products,” being “committed to investing in research and development with the aim of delivering high quality . . . products,” and of J&J’s subsidiaries having “substantial defenses,” they omitted that, (i) asbestos had repeatedly been found in the Company’s talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67, 230), and (iv) J&J had purposely influenced and manipulated regulators and scientists in order to protect the Company’s flagship product and reputation(¶¶61-62, 68-72, 78, 80, 82-86, 93-104, 223, 227, 231-232).

I. April 2015 False and Misleading Statements

284. At an April 23, 2015 Shareholders Meeting, defendant Gorsky assured investors that J&J was taking care of mothers and babies:

Johnson & Johnson is committed to helping mothers and babies, we never want to forget the needs of the world's smallest patients.

* * *

Caring inspires us day in and day out as we strive to make a difference for people who count on us the most. And as the world's largest and best healthcare company in the world, we're committed to reaching more people in more places in more ways. ***We're helping people ultimately live longer, healthier, and happier lives.***

285. Defendants' statements, as alleged in ¶284, were false and misleading. Instead of being committed to mothers and babies, helping people live longer and happier lives, or "striv[ing] to make a difference for people," defendants were continuing J&J's longstanding fraudulent scheme to protect the image of Baby Powder's and the Company's reputation, concealing that (i) asbestos had repeatedly been found in the Company's talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67, 230), and (iv) J&J had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation(¶¶61-62, 68-72, 78, 80, 82-86, 93-104, 223, 227, 231-232). Despite the

numerous red flags raised internally at the Company, J&J continued to sell its talcum powders and failed to use proper methods for testing its talc.

J. May to October 2015 False and Misleading Statements

286. On May 1, 2015, J&J filed its first quarter of 2015 (“1Q15”) Form 10-Q with the SEC. Defendants disclosed that some of J&J’s subsidiaries were involved in product liability litigation, but also represented that the subsidiaries had “substantial defenses”:

Certain subsidiaries of Johnson & Johnson are involved in numerous product liability claims and lawsuits involving multiple products. Claimants in these cases seek substantial compensatory and, where available, punitive damages. While *these subsidiaries believe they have substantial defenses*, it is not feasible to predict the ultimate outcome of litigation. The Company has established product liability accruals in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. In addition, product liability accruals can represent projected product liability for thousands of claims around the world, each in different litigation environments and with different fact patterns. Changes to the accruals may be required in the future as additional information becomes available.²⁹

287. Defendants’ statements, as alleged in ¶286, were false and misleading. While defendants boasted of J&J’s subsidiaries having “substantial defenses,” they omitted that (i) asbestos had repeatedly been found in the Company’s talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to

²⁹ These statements were also made in J&J’s second quarter of 2015 (“2Q15”) and third quarter of 2015 (“3Q15”) Form 10-Qs (filed July 31, 2015 and October 30, 2015, respectively).

find ways to remove tremolite from its talc (§§58, 60, 228), (iii) J&J never adopted concentration methods that could detect the asbestos (§§63-67, 230), and (iv) J&J had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation (§§61-62, 68-72, 78, 80, 82-86, 93-104, 223, 227, 231-232).

K. December 2015 False and Misleading Statements

288. As of December 25, 2015, the Company had updated its website entitled "Our Safety & Care Commitment," stating the following:

Any amount of talc used in a consumer product is required to be asbestos-free and has been since the 1970s – though misperceptions still exist that talc products contain asbestos, a substance with links to cancer. JOHNSON'S® Baby Powder products contain only U.S. Pharmacopeial (USP) grade talc which meets the highest quality, purity and compliance standards. The talc used in all our global products is carefully selected and processed to be asbestos-free, and we confirm this with regular testing. The U.S. Food and Drug Administration (FDA) has also tested and confirmed the purity of our talc.

Another misperception is that talc in baby powder can be easily inhaled or absorbed into the body. We always recommend not using talc around a baby's face or mouth, and to further protect your baby, *we precisely mill our JOHNSON'S talc products to a relatively large size to decrease the potential to be inhaled or absorbed into the body.*

Decades of Safety

Our confidence in using talc reflects *more than 30 years of research by independent scientists, review boards and global authorities, which have concluded that talc can be used safely in personal care products. Various government agencies and other bodies also have examined talc to determine the potential for any safety risks, and none have concluded that there are safety risks.* In fact, no

regulatory agency has ever required a change in labeling to reflect any safety risk from talc powder products.

* * *

Among the agencies that have examined talc are the U.S. Department of Health and Human Services and the U.S. FDA. As recently as 2014, the FDA again reviewed the safety data on talc and did not find “any new compelling literature data or new scientific evidence.”

Cosmetic talc is not included in the most recent Report on Carcinogens, which is published by the U.S. National Toxicology Program (NTP). NTP is a globally-recognized program and is formed from parts of several different government agencies, including the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA).

In addition to government health authorities, our own toxicology teams are also responsible for evaluating any new research published on talc, and ***at times we may ask outside experts for an independent perspective on new or existing studies. We have carefully assessed all available data on talc and consumers can feel confident that the overwhelming body of research and clinical evidence continues to support the safety of cosmetic talc.***

* * *

Our Position on Talc

At Johnson & Johnson Consumer Inc., our confidence in using talc is based on a ***long history of safe use and more than 30 years of research by independent researchers, scientific review boards and global regulatory authorities. Various agencies and governmental bodies have examined whether talc is a carcinogen, and none have concluded that it is. With over 100 years of use, few ingredients have the same demonstrated performance, mildness and safety profile as cosmetic talc.***

289. Defendants’ statements, as alleged in ¶288, were false and misleading.

As alleged in ¶¶128 and 224, defendants J&J and Goodrich knew that talc did not

have “a long history of safe use” after “over 100 years of use,” as the earlier draft language for the website in Goodrich’s possession illustrated that the 100 years of use was not safe and even noted that “I don’t think we can link cosmetic talc to 100 years of use.” And while the website boasts of talc’s “long history of safe use,” creating the impression that J&J’s talc has always been asbestos-free, as alleged in ¶¶128 and 224, Goodrich’s own draft admits that “we cannot say ‘always.’” In addition, these statements – as well as the representations regarding talc’s “safety profile,” “purity,” and asbestos-free nature, the representation that J&J’s talc is “precisely milled” and “carefully selected and processed to be asbestos-free, [confirmed] with regular testing,” and the representation that “[a]ny amount of talc used in a consumer product is required to be asbestos-free and has been since the 1970s” were false and misleading as they omitted that: (i) asbestos had repeatedly been found in the Company’s talc and powders(¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), and (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67, 230).

290. Defendants’ representations, as alleged in ¶288, that: (i) “more than 30 years of research by independent scientists, review boards and global authorities” supported the safety of talc, (ii) “the overwhelming body of research and clinical evidence” supports cosmetic talc’s safety, (iii) “consumers can feel confident” about

the safety of talc based on J&J's "careful[] assess[ment] [of] all available data," and (iv) "none" of the "[v]arious government agencies and other bodies" have concluded there are any safety risks with talc usage, were false and misleading when made. As alleged in ¶¶131 and 225, J&J acknowledged internally that scientific sources not included on the website were actually "not as definitive or supportive and could be interpreted as suggesting a causal effect" and that "[e]ven some of the studies we cite send mixed messages." And as alleged in ¶¶131 and 225, J&J acknowledged internally that even one of the studies cited by J&J admitted that "'perineal talc use may modestly increase the risk of invasive serous ovarian cancers.'" In addition, these statements, as well the statement regarding "outside experts [with] independent perspective[s]," omitted that (i) asbestos had repeatedly been found in the Company's talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67, 230), and (iv) J&J had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation (¶¶61-62, 68-72, 78, 80, 82-86, 93-104, 223, 227, 231-232).

291. Similarly, defendants' statement regarding the FDA, as alleged in ¶288, was materially misleading, as the website failed to disclose that J&J had falsely assured the FDA that its talc and powders were free of asbestos. ¶¶56, 227-228. And

defendants’ statement regarding the absence of talc in the RoC omitted J&J’s own internal recognition that this was a “direct result” of the Company’s efforts at influencing regulators. ¶104.

292. The “Our Safety and Care Commitment” website also contained the following statement from defendant Casalvieri, Director of Toxicology and Skincare, JJCI:

As a toxicologist in our Consumer business, my job is to make certain a product is safe by assessing whether any ingredient in that product poses a risk. *We want to assure women and caregivers who use our talc products that numerous studies support its safety, and these include assessments by external experts in addition to our company testing. Many research papers and epidemiology studies have specifically evaluated talc and perineal use and these studies have found talc to be safe.*

293. The statements by defendant Casalvieri, as alleged in ¶292, were false and misleading. While Casalvieri represented that “company testing,” “numerous studies” and “assessments by external experts” support[ed] [talc’s] safety,” and that “[m]any research papers and epidemiology studies . . . have found talc to be safe,” she omitted that (i) asbestos had repeatedly been found in the Company’s talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67, 230), and (iv) J&J had purposely influenced and manipulated regulators and scientists in order to protect the

Company's flagship product and reputation (¶¶61-62, 68-72, 78, 80, 82-86, 93-104, 223, 227, 231-232).

L. February 2016 False and Misleading Statements

294. In a February 23, 2016 *Reuters* article, Company spokeswoman Goodrich was quoted:

We have no higher responsibility than the health and safety of consumers, and we are disappointed with the outcome of the trial. We sympathize with the plaintiff's family but *firmly believe the safety of cosmetic talc is supported by decades of scientific evidence.*

295. But the statement by Goodrich and J&J, as alleged in ¶294, was false and misleading. As alleged in ¶¶131 and 225, J&J acknowledged internally that some of the scientific sources were actually “not as definitive or supportive and could be interpreted as suggesting a causal effect” between ovarian cancer and talc and that “[e]ven some of the studies we cite send mixed messages.” And as alleged in ¶¶131 and 225, J&J acknowledged internally that even one of the studies cited by J&J admitted that ““perineal talc use may modestly increase the risk of invasive serous ovarian cancers.”” In addition, the statement alleged in ¶294 was false and misleading in that it failed to disclose that (i) asbestos had repeatedly been found in the Company's talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67, 230), and (iv) J&J had purposely influenced and manipulated regulators and scientists

in order to protect the Company's flagship product and reputation (¶¶61-62, 68-72, 78, 80, 82-86, 93-104, 223, 227, 231-232).

296. On February 24, 2016, J&J filed its 2015 10-K with the SEC ("2015 10-K"). Signed by defendants Gorsky and Caruso, the 2015 10-K again represented that J&J "remain[ed]" committed" to "delivering high quality" and "improving existing products":

Research activities represent a significant part of the Company's businesses. Research and development expenditures relate to the processes of discovering, testing and developing new products, *improving existing products*, as well as demonstrating product efficacy and regulatory compliance prior to launch. *The Company remains committed to investing in research and development with the aim of delivering high quality* and innovative products.

297. In its 2015 10-K, defendants disclosed that some of J&J's subsidiaries were involved in product liability litigation, but also represented that they had "substantial defenses":

Certain subsidiaries of Johnson & Johnson are involved in numerous product liability claims and lawsuits involving multiple products. Claimants in these cases seek substantial compensatory and, where available, punitive damages. While *these subsidiaries believe they have substantial defenses*, it is not feasible to predict the ultimate outcome of litigation. The Company has established accruals for product liability claims and lawsuits in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. The Company accrues an estimate of the legal defense costs needed to defend each matter. For certain of these matters, the Company has accrued additional amounts such as estimated costs associated with settlements, damage and other losses. Product liability accruals can represent projected product liability for thousands of claims around the world, each in different litigation environments and with different fact

patterns. Changes to the accruals may be required in the future as additional information becomes available.

298. Defendants' statements, as alleged in ¶¶296 and 297, were false and misleading. While defendants boasted of "improving existing products," being "committed to investing in research and development with the aim of delivering high quality . . . products," and of J&J's subsidiaries having "substantial defenses," they omitted that: (i) asbestos had repeatedly been found in the Company's talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67, 230), and (iv) J&J had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation (¶¶61-62, 68-72, 78, 80, 82-86, 93-104, 223, 227, 231-232).

299. On February 24, 2016, J&J created a page on its website, entitled "The Facts About Talc Safety." There, the Company stated:

Baby Powder made from cosmetic talc is one of JOHNSON's oldest products and a longtime part of baby care rituals. JOHNSON's Baby Powder continues to be popular with adults as well, and in many parts of the world, it remains an essential part of the makeup and skin care routines. ***With over 100 years of use, few ingredients have the same demonstrated performance, mildness and safety profile as cosmetic talc.***

We wanted to take this opportunity to share the facts about talc, ***so you're well-informed.***

- ***JOHNSON’s talc products do not contain asbestos.*** A frequent misperception is that JOHNSON’s Baby Powder contains talc made with asbestos, a substance classified as cancer-causing. ***Since the 1970s, talc used in consumer products has been required to be asbestos-free.*** JOHNSON’S® Baby Powder products contain only U.S. Pharmacopeia (USP) grade talc, which meets the highest quality, purity and compliance standards.
- ***The safety of talc is based on a long history of safe use and decades of research by independent researchers and scientific review boards.*** Talc is accepted as safe for use in cosmetic and personal care products by the European Union, Canada and many other countries around the world, among them Argentina, Brazil, China, India, Israel, South Africa, Turkey and Indonesia. The U.S. Center for Disease Control (CDC), which identifies potential risk factors for many diseases, has not identified talc as a risk factor for ovarian cancer.
- The Nurses’ Health Study (2010) and the Women’s Health Initiative Observational Cohort (2014), the only two large-scale prospective studies looking at talc and ovarian cancer, found no causal relationship between talc and ovarian cancer.

* * *

The grade of talc used in cosmetics is of high purity, comparable to that used for pharmaceutical applications, and is free from asbestos and asbestiform fibers. Cosmetic grade talc is only mined from select deposits from certified locations, and milled to relatively large, non-respirable particles size.

* * *

Our sources for talc undergo comprehensive qualification. The incoming talc is routinely evaluated using a sophisticated battery of tests designed to ensure quality, safety, and compliance with all global standards.

300. Defendants’ statements, as alleged in ¶299, were false and misleading and were not written and communicated to keep investors “well-informed.” While

defendants' claimed that cosmetic talc had "over 100 years of use," as alleged in ¶¶128 and 224, J&J's own internal document acknowledges that "I don't think we can link cosmetic talc to 100 years of use." This statement was false and misleading for other reasons, as were the representations (i) regarding talc's "long history of safe use," "safety profile," and "high purity," (ii) that cosmetic talc "is free from asbestos and asbestiform fibers," "only mined from select deposits from certified locations," and "milled to relatively large, non-respirable particles size," (iii) that talc used in consumer products "has been required to be asbestos-free" "[s]ince the 1970s," (iv) that J&J's "sources for talc undergo comprehensive qualification" and that "incoming talc is routinely evaluated using a sophisticated battery of tests designed to ensure . . . safety," (v) J&J's "talc products do not contain asbestos," and (vi) that it is a "misperception . . . that JOHNSON'S Baby Powder contains talc made with asbestos." These statements concealed that (i) asbestos had repeatedly been found in the Company's talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67, 230), and (iv) J&J had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation (¶¶61-62, 68-72, 78, 80, 82-86, 93-104, 223, 227, 231-232). In addition, defendants' statements created the

impression that J&J's talc has always been asbestos-free, but as alleged in ¶¶128 and 224, J&J knew internally that "we cannot say 'always.'"

301. Defendants' representation, as alleged in ¶299, that "decades of research by independent researchers and scientific review boards" supported "[t]he safety of talc," was also false and misleading, as defendants omitted that, as alleged in ¶¶131 and 225, J&J acknowledged internally that some of the scientific sources were actually "not as definitive or supportive and could be interpreted as suggesting a causal effect" between ovarian cancer and talc and that "[e]ven some of the studies we cite send mixed messages." And as alleged in ¶¶131 and 225, J&J internally acknowledged that one of the studies cited by J&J admitted that "perineal talc use may modestly increase the risk of invasive serous ovarian cancers." In addition, the statement about "decades of research" was false and misleading because it failed to disclose that (i) asbestos had repeatedly been found in the Company's talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67, 230), and (iv) J&J had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation (¶¶61-62, 68-72, 78, 80, 82-86, 93-104, 223, 227, 231-232).

M. May 2016 False and Misleading Statements

302. On May 2, 2016, J&J and defendant Goodrich made the following representations in a press release posted on J&J's website:

Unfortunately, *the jury's decision goes against 30 years of studies by medical experts around the world that continue to support the safety of cosmetic talc.* We understand that women and families affected by ovarian cancer are searching for answers, and we deeply sympathize with all who have been affected by this devastating disease with no known cause. *Johnson & Johnson has always taken questions about the safety of our products extremely seriously. Multiple scientific and regulatory reviews have determined that talc is safe for use in cosmetic products and the labeling on Johnson's Baby Powder is appropriate. For over 100 years, Johnson & Johnson has provided consumers with a safe choice for cosmetic powder products* and we will continue to work hard to exceed consumer expectations and evolving product preferences.

303. Also on May 2, 2016, J&J published "A Message About Talc" on its website. In the release, J&J again promised that its talc products were safe – omitting any mention of asbestos – and assured that J&J "did the things you expect from a company you trust":

30 years of studies by medical experts around the world, science, research and clinical evidence continues to support the safety of cosmetic talc. We first offered JOHNSON'S® Baby Powder as a product choice more than 100 years ago because we were confident in the safety of talc. And today, we continue to manufacture and sell JOHNSON'S® Baby Powder with talc because we remain completely confident in its safety. We remain committed to safety and innovation, and will continue to work hard to exceed consumer expectations and evolving product preferences. This commitment to innovation led to the introduction of JOHNSON'S® Baby Powder made with cornstarch as an additional option for consumers nearly forty years ago.

Everyone at Johnson & Johnson sympathizes deeply with the women and families who have been affected by ovarian cancer, a devastating disease with no known cause. We know the women and families affected are searching for answers and want to understand the science.

Safety

When concerns about an association between talc and ovarian cancer were first raised in the early 1980s, Johnson and Johnson took them very seriously and did the things you expect from a company you trust including:

- ***Testing*** to ensure that the talc in JOHNSON'S® Baby Powder meets the highest Quality standards (US Pharmacopeia)
- ***Engaging with the FDA, regulatory agencies, and governments*** around the world
- ***Monitoring studies and all available information*** examining the safety of talc
- ***Talking with independent consultants*** from outside our company about their point of view on the safety of talc.

After 30 years of studies by medical experts around the world, science, research and clinical evidence continues to support the safety of cosmetic talc. Two widely-accepted, very large studies which followed women over a period of time – the Nurses' Health Study by the Harvard School of Public Health published in 2009 and the Women's Health Initiative Observational Cohort by the U.S. National Institutes of Health published in 2014 – found no association between talc and ovarian cancer. We also know that some epidemiology studies have reported an association between talc and ovarian cancer. However, ***various governmental and non-governmental agencies as well as other expert panels have reviewed and analyzed all available data, and none have concluded that talc can cause cancer.***

Concerns about the possible association between cosmetic talc with ovarian cancer increased after recent jury verdicts in the United States. It is natural for trial verdicts to raise questions about the product involved, and it's also important to distinguish jury verdicts – in the

United States – from regulatory rulings or rigorous scientific findings. ***Johnson & Johnson has always taken questions about the safety of our products extremely seriously***, especially concerns about products like JOHNSON’S® Baby Powder that families have trusted for generations. We continue to believe in the safety of JOHNSON’S® Baby Powder containing talc and we trust our consumers to make their own decisions – which are why we want to provide the scientific support for the safety of talc. Our goal is always to meet our consumer’s needs and we are fortunate to have had this opportunity for more than 130 years.

304. Defendants’ statements, as alleged at ¶¶302-303, that “Johnson & Johnson has provided consumers with a safe choice for cosmetic powder products” “[f]or over 100 years,” and that J&J first sold Baby Powder “more than 100 years ago because we were confident in the safety of talc” and “we remain completely confident in its safety,” were false and misleading. In truth, as alleged in ¶¶128 and 224, defendant J&J acknowledged internally that its talcum powders had not been “safe” for over 100 years, and indeed, J&J could not even “link cosmetic talc to 100 years of use.” The statements also created the impression that J&J’s talc has historically been safe, when in fact J&J knew that when it came to asbestos in the Company’s talcum powders, it could not say it was ““always”” asbestos-free. ¶¶128 and 224. These statements were false and misleading because they omitted that: (i) asbestos had repeatedly been found in the Company’s talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67, 230), and (iv) J&J had purposely influenced and

manipulated regulators and scientists in order to protect the Company's flagship product and reputation (¶¶61-62, 68-72, 78, 80, 82-86, 93-104, 150-54, 223, 227, 231-232).

305. Defendants' statements, as alleged in ¶¶302-303, that (i) "30 years of studies by medical experts around the world" "science, research and clinical evidence" "support the safety of cosmetic talc," (ii) "[m]ultiple scientific and regulatory reviews have determined that talc is safe . . . and the labeling on Johnson's Baby Powder is appropriate," and (iii) out of "various governmental and non-governmental agencies" and "expert panels," "none have concluded that talc can cause cancer" even after they "reviewed and analyzed all available data," were false and misleading. As alleged in ¶¶131 and 225, J&J knew that some scientific sources "could be interpreted as suggesting a causal effect" and that "[e]ven some of the studies [it] cite[d] send mixed messages." Further, as alleged in ¶¶131 and 225, J&J knew that research it cited had actually determined that "perineal talc use may modestly increase the risk of invasive serous ovarian cancers." These statements were also false and misleading because they omitted that: (i) asbestos had repeatedly been found in the Company's talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67, 230), (iv) J&J had purposely influenced and manipulated regulators and scientists in order to protect the

Company's flagship product and reputation (¶¶61-62, 68-72, 78, 80, 82-86, 93-104, 150-154, 223, 227, 231-232), and (v) J&J had misled the FDA less than two months prior (¶¶150-154).

306. Defendants' representations as alleged in ¶¶302 and 303 that (i) "Johnson & Johnson has always taken questions about the safety of [Johnson's Baby Powder] extremely seriously," (ii) J&J "remain[ed] committed to safety," and (iii) J&J took "concerns about an association between talc and ovarian cancer" "very seriously and did the things you expect from a company you trust," including testing, engaging with the FDA and other regulators, monitoring "all available information," and "[t]alking with independent consultants," were also false and misleading. These statements omitted that: (i) asbestos had repeatedly been found in the Company's talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67, 230), (iv) J&J had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation (¶¶61-62, 68-72, 78, 80, 82-86, 93-104, 150-154, 223, 227, 231-232), and (v) J&J had misled the FDA less than two months prior (¶¶150-154).

307. On May 10, 2016, J&J filed its 1Q16 Form 10-Q with the SEC. Defendants disclosed that some of J&J's subsidiaries were involved in product

liability litigation, but also represented that the subsidiaries had “substantial defenses”:

Certain subsidiaries of Johnson & Johnson are involved in numerous product liability claims and lawsuits involving multiple products. Claimants in these cases seek substantial compensatory and, where available, punitive damages. While *these subsidiaries believe they have substantial defenses*, it is not feasible to predict the ultimate outcome of litigation. The Company has established accruals for product liability claims and lawsuits in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. The Company accrues an estimate of the legal defense costs needed to defend each matter when those costs are probable and can be reasonably estimated. For certain of these matters, the Company has accrued additional amounts such as estimated costs associated with settlements, damages and other losses. Product liability accruals can represent projected product liability for thousands of claims around the world, each in different litigation environments and with different fact patterns. Changes to the accruals may be required in the future as additional information becomes available.

* * *

Claims for personal injury have been made against Johnson & Johnson Consumer Inc. and Johnson & Johnson arising out of the use of JOHNSON’S® Baby Powder. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Lawsuits have been primarily filed in state courts in Missouri and New Jersey. The Company has established an accrual for defense costs in connection with product liability litigation associated with JOHNSON’S® Baby Powder. Changes to this accrual may be required in the future as additional information becomes available.

308. Defendants’ statements, as alleged in ¶307, were false and misleading.

While defendants boasted of J&J’s subsidiaries having “substantial defenses” and disclosed the existence of talc-related litigation, they omitted that: (i) asbestos had

repeatedly been found in the Company's talc and powders (§§55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (§§58, 60, 228), (iii) J&J never adopted concentration methods that could detect the asbestos (§§63-67, 230), and (iv) J&J had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation (§§61-62, 68-72, 78, 80, 82-86, 93-104, 150-154, 223, 227, 231-232).

309. On May 18, 2016, Ghaim, the Chief Technology Officer of J&J Consumer, made further assurances during the Consumer and Medical Devices Business Review:

I'm going to start by saying there's a general assumption that people have natural is safe and most of the data we have actually that's not true. So there is a balance in terms of what products, what type of safety do we need to continue to build.

And all of our products, especially when we start with Baby, the number of safety studies that we tend to do before we even put it in any of our product is a starting point. But we also understand that the natural trend continues to be a big opportunity.

So we're working to that in terms of not just picking naturals but make sure that there is a benefit to it, make sure that it's safe, make sure that we can source it the right way because that's one of the biggest challenges. You can get natural ingredients but you can't guarantee that one lot to the next is actually consistently safe.

So for us I think we can see the trend. But at the same time ***we're being very careful in terms of what raw materials we select, what type of safety studies that are needed.*** Because more than anything else safety is the number one area that we need to continue to focus.

310. Defendants' representation, as alleged in ¶309, that "we're being very careful in terms of what raw materials we select, what type of safety studies that are needed," was false and misleading. This statement concealed that: (i) asbestos had repeatedly been found in the Company's talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), and (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67, 230).

N. June 2016 False and Misleading Statements

311. On June 19, 2016, defendant Glasgow, VP of R&D at JJCI, stated the following in an editorial in the *Houston Chronical*:

At Johnson & Johnson Consumer Inc., ***we are guided by the medical facts and science*** when it comes to our products. ***Cosmetic talc is safe, and 30 years of scientific studies and regulatory reviews have shown this to be true.***

This counters the claims of so-called experts, paid to testify on behalf of plaintiffs, who say decisions by juries should trump the overwhelming scientific data.

We first offered Johnson's Baby Powder as a product choice more than 100 years ago. Today, we continue to manufacture and sell Johnson's Baby Powder with talc because ***the science supports its safety.***

Ovarian cancer is a devastating disease, and we recognize that women and families affected by this disease are searching for answers and want to understand the science. When concerns about an association between talc use and ovarian cancer were raised, ***we started doing the things you expect from a company you trust, including testing*** to ensure the talc in our products meets the highest quality standards, ***meeting with regulators and governments*** around the world, ***looking closely at the***

studies and available information, and talking with independent consultants.

The facts are clear. The studies, science, research and clinical evidence have continued to support the safety of cosmetic talc. Most recently, two widely-accepted, very large studies which followed women over a long period of time – the Nurses’ Health Study by the Harvard School of Public Health published in 2009 and the Women’s Health Initiative Observational Cohort by the U.S. National Institutes of Health published in 2014 – found no association between talc use for feminine hygiene and ovarian cancer.

There have been some studies that reported an association between talc and ovarian cancer.

In my job as a scientist, terms and words matter when it comes to studies, and an “association” does not mean something causes a specific result. Additionally, ***many in the scientific community have concluded that the data from those studies are inconclusive because of how the studies were conducted. Various governmental and non-governmental agencies, such as the U.S. Food and Drug Administration (FDA) and National Cancer Institute, as well as other expert panels have reviewed and analyzed the available data and concluded that there is insufficient evidence linking talc use to ovarian cancer.***

Johnson’s Baby Powder products contain only U.S. Pharmacopeia grade talc to ensure ***it meets the highest quality, purity and compliance standards. We also carefully select and process the talc used in all our global production to be asbestos-free, and have confirmed this with regular testing since the 1970s.*** The U.S. FDA has also independently tested and confirmed the purity of the talc used in our cosmetic products.

We trust our consumers to make their own decisions, which is why we will continue to provide consumers with the facts. As a scientist, and most importantly, as a parent, I can tell you ***the science is clear – cosmetic talc is, and has been, safe for use and that is the most important guiding principle for every product Johnson & Johnson Consumer Inc. offers to consumers and patients.***

312. Defendants’ representations, as alleged in ¶311, that: (i) “[c]osmetic talc is safe,” (ii) Johnson’s Baby Powder’s talc meets “the highest” purity standard, and (iii) J&J “carefully select[s] and process[es] the talc used in all [its] global production to be asbestos-free, and have confirmed this with regular testing since the 1970s,” were false and misleading. These statements concealed that: (i) asbestos had repeatedly been found in the Company’s talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), and (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67, 230).

313. Defendants’ representations, as alleged in ¶311, that (i) J&J did “the things you expect from a company you trust” “[w]hen concerns about an association between talc use and ovarian cancer were raised,” including testing, meeting with regulators, looking at “available information,” and talking with “independent consultants,” (ii) J&J’s Consumer Division is “guided by the medical facts and science,” and (iii) safety “is the most important guiding principle for every product Johnson & Johnson Consumer Inc. offers to consumers and patients,” were false and misleading. These statements concealed that: (i) asbestos had repeatedly been found in the Company’s talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67,

230), and (iv) J&J had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation (¶¶61-62, 68-72, 78, 80, 82-86, 93-104, 150-154, 223, 227, 231-232).

314. Defendants' representations, as alleged in ¶311, that: (i) "30 years of scientific studies and regulatory reviews" have shown that "[c]osmetic talc is safe," (ii) "the science supports [Johnson's Baby Powder's] safety," (iii) "[t]he facts are clear" that "[t]he studies, science, research and clinical evidence have continued to support the safety of cosmetic talc," (iv) "the science is clear – cosmetic talc is, and has been, safe for use," and (v) "[v]arious governmental and non-governmental agencies [including the FDA], as well as other expert panels, have reviewed and analyzed the available data and concluded that there is insufficient evidence linking talc use to ovarian cancer," were false and misleading. As alleged in ¶¶131 and 225, J&J knew that some scientific sources were actually "not as definitive or supportive and could be interpreted as suggesting a causal effect" between ovarian cancer and talc and that "[e]ven some of the studies we cite send mixed messages." And as alleged in ¶¶131 and 225, J&J acknowledged internally that even one of the studies it cited had determined that "perineal talc use may modestly increase the risk of invasive serous ovarian cancers." In addition, the statements failed to disclose that: (i) asbestos had repeatedly been found in the Company's talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to

remove tremolite from its talc (§§58, 60, 228), (iii) J&J never adopted concentration methods that could detect the asbestos (§§63-67, 230), (iv) J&J had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation (§§61-62, 68-72, 78, 80, 82-86, 93-104, 150-154, 223, 227, 231-232), and (v) J&J had misled the FDA less than three months prior (§§150-154).

O. August to November 2016 False and Misleading Statements

315. On August 4, 2016, J&J filed its second quarter of 2016 ("2Q16") Form 10-Q with the SEC. Defendants disclosed that J&J and some of J&J's subsidiaries were involved in product liability litigation, but also represented that the Company had "substantial defenses":

Johnson & Johnson and certain of its subsidiaries are involved in numerous product liability claims and lawsuits involving multiple products. Claimants in these cases seek substantial compensatory and, where available, punitive damages. While *the Company believes it has substantial defenses*, it is not feasible to predict the ultimate outcome of litigation. The Company has established accruals for product liability claims and lawsuits in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. The Company accrues an estimate of the legal defense costs needed to defend each matter when those costs are probable and can be reasonably estimated. For certain of these matters, the Company has accrued additional amounts such as estimated costs associated with settlements, damages and other losses. Product liability accruals can represent projected product liability for thousands of claims around the world, each in different litigation environments and with different fact patterns. Changes to the accruals may be required in the future as additional information becomes available.

* * *

Claims for personal injury have been made against Johnson & Johnson Consumer Inc. and Johnson & Johnson arising out of the use of JOHNSON'S® Baby Powder. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Lawsuits have been primarily filed in state courts in Missouri and New Jersey. The Company has established an accrual for defense costs in connection with product liability litigation associated with JOHNSON'S® Baby Powder. Changes to this accrual may be required in the future as additional information becomes available.

316. On November 4, 2016, J&J filed its third quarter of 2016 ("3Q16") Form 10-Q with the SEC. Defendants again disclosed that J&J and some of J&J's subsidiaries were involved in product liability litigation, but also represented that the Company had "substantial defenses":

Johnson & Johnson and certain of its subsidiaries are involved in numerous product liability claims and lawsuits involving multiple products. Claimants in these cases seek substantial compensatory and, where available, punitive damages. While *the Company believes it has substantial defenses*, it is not feasible to predict the ultimate outcome of litigation. The Company has established accruals for product liability claims and lawsuits in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. The Company accrues an estimate of the legal defense costs needed to defend each matter when those costs are probable and can be reasonably estimated. For certain of these matters, the Company has accrued additional amounts such as estimated costs associated with settlements, damages and other losses. Product liability accruals can represent projected product liability for thousands of claims around the world, each in different litigation environments and with different fact patterns. Changes to the accruals may be required in the future as additional information becomes available.

* * *

Claims for personal injury have been made against Johnson & Johnson Consumer Inc. and Johnson & Johnson arising out of the use of JOHNSON'S® Baby Powder. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Lawsuits have been primarily filed in state courts in Missouri, New Jersey and California. In addition, a federal multi-district litigation proceeding has been created for this litigation in the District Court of New Jersey. The Company has established an accrual for defense costs in connection with product liability litigation associated with JOHNSON'S® Baby Powder. Changes to this accrual may be required in the future as additional information becomes available.

317. Defendants' statements, as alleged in ¶¶315-316, were false and misleading. While defendants boasted of having "substantial defenses" and disclosed the existence of talc-related litigation, they omitted that: (i) asbestos had repeatedly been found in the Company's talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67, 230), (iv) J&J had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation (¶¶61-62, 68-72, 78, 80, 82-86, 93-104, 150-154, 223, 227, 231-232).

P. December 2016 False and Misleading Statements

318. On December 30, 2016, J&J touted the safety and effectiveness of talc in its products on its website³⁰ stating in pertinent part:

³⁰ See <https://www.safetyandcarecommitment.com/Ingredients/Talc>.

In our products

We continue to use talc in our products because *decades of science have reaffirmed its safety*. Because of its safety and effectiveness, we confidently include pharmaceutical grade talc in our products. Your trust in our products and your confidence using them every day is a huge responsibility – that’s why *we only use ingredients in our products deemed safe by the latest science*.

Science, research, clinical evidence and 30 years of studies by medical experts around the world continue to support the safety of cosmetic talc. Health authorities in the U.S. and around the world have reviewed the data. Talc is accepted for . . . use in countries around the world, including the United States, European Union, Canada, Argentina, Brazil, China, India, Israel, South Africa, Turkey, and Indonesia.

When you read a new study or expert opinion, it’s easy to be swayed one way or another. *We take any questions about our product’s safety seriously* and as a result have dug deep into the evidence and science on talc.

319. Defendants’ statement, as alleged in ¶318, that J&J “take[s] any questions about [its] product’s safety seriously,” was false and misleading, as it concealed that: (i) asbestos had repeatedly been found in the Company’s talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67, 230), (iv) J&J had purposely influenced and manipulated regulators and scientists in order to protect the Company’s flagship product and reputation (¶¶61-62, 68-72, 78, 80, 82-86, 93-104, 150-154, 223, 227, 231-232), and (v) J&J had misled the FDA in 2016 (¶¶150-154).

320. Defendants’ assurances, as alleged in ¶¶18, that “decades of science have reaffirmed [the] safety” of “talc in [J&J’s] products,” “[s]cience, research, clinical evidence and 30 years of studies by medical experts around the world continue to support the safety of cosmetic talc,” and J&J “only use[s] ingredients in [its] products deemed safe by the latest science,” were false and misleading. As alleged in ¶¶131 and 225, J&J knew that some scientific sources were actually “not as definitive or supportive and could be interpreted as suggesting a causal effect” between ovarian cancer and talc and that “[e]ven some of the studies we cite send mixed messages.” And as alleged in ¶¶131 and 225, J&J also knew that one of the studies it cited had determined that ““perineal talc use may modestly increase the risk of invasive serous ovarian cancers.”” In addition, the statements failed to disclose that: (i) asbestos had repeatedly been found in the Company’s talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67, 230), and (iv) J&J had purposely influenced and manipulated regulators and scientists in order to protect the Company’s flagship product and reputation (¶¶61-62, 68-72, 78, 80, 82-86, 93-104, 150-154, 223, 227, 231-232).

Q. January 2017 False and Misleading Statements

321. On January 24, 2017, J&J's website entitled "The facts on talcum powder safety" contained a statement by Glasgow, the VP of R&D at J&J's consumer division. There, Glasgow omitted that the Company had received numerous reports of asbestos in its products:

When it comes to the safety of the products we make, we're just like you
 . . .

We want all the information we can get. We seek out the guidance of experts and we monitor the latest science to see if it impacts any of our products. We also listen to the people who use our products so we can take their experiences into account. ***Safety is a priority for all of our consumer products because they go into your home and into ours. Safety is a value we all share.***

With all the types of information we use to make products, ***there is no information more important than our research on scientific data and safety.*** We go beyond the findings of a single study because we must ensure we've assembled ***all of the available data*** from multiple scientific areas to reach conclusions based on evidence. One opinion or study can't outweigh ***decades of conclusive, scientific, evidence-based findings.*** As a scientist and, equally important, as a parent myself, ***I can tell you the science is clear: Cosmetic talc is, and has been, safe for use in consumer products.***

We are all mothers, fathers, and consumers ourselves; we understand and take seriously our responsibility to give you the information you need to make your own decisions. We created this site to help you find the facts about talc more easily. You'll learn where talc comes from, how it is used in everyday products, and why ***it is safe to use as part of your personal care routine.*** We first offered JOHNSON'S® Baby Powder as a product choice more than 100 years ago. Today, our consumer division continues to manufacture and sell JOHNSON'S® Baby Powders with ingredients like talc and cornstarch. We choose to include these ingredients not simply because we've used them for decades. ***We include them because decades of scientific work***

support their safety. We hope that by reviewing this collection of facts about talc, you'll feel as confident in its safety and efficacy as we do.

322. Defendants' statements, as alleged in ¶321, that J&J made safety a priority and that "there is no information more important than . . . research on scientific data and safety," were false and misleading. In truth, defendants had and were continuing to conceal the dangers inherent in the Company's talcum powders. Indeed, defendants failed to disclose that: (i) asbestos had repeatedly been found in the Company's talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67, 230), (iv) J&J had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation (¶¶61-62, 68-72, 78, 80, 82-86, 93-104, 150-154, 223, 227, 231-232), and (v) J&J had misled the FDA in 2016 (¶¶150-154).

323. Defendants' statements, as alleged in ¶321, that: (i) "all of the available data" and "decades of conclusive, scientific, evidence-based findings" supported the safety of cosmetic talc, (ii) "the science is clear: Cosmetic talc is, and has been, safe for use in consumer products," (iii) talc "is safe to use as part of your personal care routine," and (iv) "decades of scientific work" "support[s] [talc's] safety," were false and misleading. J&J acknowledged internally that some scientific sources were actually "not as definitive or supportive and could be interpreted as suggesting a

causal effect” between ovarian cancer and talc and that “[e]ven some of the studies we cite send mixed messages.” ¶¶131 and 225. And as alleged in ¶¶131 and 225, J&J knew that one of the studies it cited had determined that “perineal talc use may modestly increase the risk of invasive serous ovarian cancers.” In addition, the statements failed to disclose that: (i) asbestos had repeatedly been found in the Company’s talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67, 230), and (iv) J&J had purposely influenced and manipulated regulators and scientists in order to protect the Company’s flagship product and reputation (¶¶61-62, 68-72, 78, 80, 82-86, 93-104, 150-154, 223, 227, 231-232).

R. February 2017 False and Misleading Statements

324. On February 27, 2017, J&J filed its 2016 10-K with the SEC, signed by defendants Gorsky and Caruso (“2016 10-K”). In its “Cautionary Note Regarding Forward-Looking Statements,” J&J included language regarding “[p]roduct efficacy or safety concerns”:

Risks Related to Product Liability, Litigation and Regulatory Activity

- Product efficacy or safety concerns, whether or not based on scientific evidence, potentially resulting in product withdrawals, recalls, regulatory action on the part of the U.S. Food and Drug Administration (or international counterparts), declining sales and reputational damage.

325. The Company's 2016 10-K also discussed the general risks and uncertainties faced by the Company, including legal proceedings:

The Company is subject to significant legal proceedings that can result in significant expenses, fines and reputational damage.

In the ordinary course of business, Johnson & Johnson and its subsidiaries are subject to numerous claims and lawsuits involving various issues such as patent disputes, product liability and claims that their product sales, marketing and pricing practices violate various antitrust, unfair trade practices and/or consumer protection laws. The most significant of these proceedings are described in Note 21, "Legal Proceedings" under Notes to the Consolidated Financial Statements included in Item 8 of this Report. While *the Company believes it has substantial defenses in these matters*, it is not feasible to predict the ultimate outcome of litigation. The Company could in the future be required to pay significant amounts as a result of settlements or judgments in these matters, potentially in excess of accruals. The resolution of, or increase in accruals for, one or more of these matters in any reporting period could have a material adverse effect on the Company's results of operations and cash flows for that period. Furthermore, as a result of cost and availability factors, effective November 1, 2005, the Company ceased purchasing third-party product liability insurance.

Product reliability, safety and effectiveness concerns can have significant negative impacts on sales and results of operations, lead to litigation and cause reputational damage.

Concerns about product safety, whether raised internally or by regulators or consumer advocates, and whether or not based on scientific evidence, can result in safety alerts, product recalls, governmental investigations, regulatory action on the part of the FDA (or its counterpart in other countries), private claims and lawsuits, payment of fines and settlements, declining sales and reputational damage. These circumstances can also result in damage to brand image, brand equity and consumer trust in the Company's products. Product recalls have in the past, and could in the future, prompt government investigations and inspections, the shutdown of manufacturing facilities, continued product

shortages and related sales declines, significant remediation costs, reputational damage, possible civil penalties and criminal prosecution.

326. J&J's 2016 10-K disclosed that the Company and some of its subsidiaries were involved in product liability litigation, but also represented that J&J had "substantial defenses":

Johnson & Johnson and certain of its subsidiaries are involved in numerous product liability claims and lawsuits involving multiple products. Claimants in these cases seek substantial compensatory and, where available, punitive damages. *While the Company believes it has substantial defenses*, it is not feasible to predict the ultimate outcome of litigation. The Company has established accruals for product liability claims and lawsuits in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. The Company accrues an estimate of the legal defense costs needed to defend each matter when those costs are probable and can be reasonably estimated. For certain of these matters, the Company has accrued additional amounts such as estimated costs associated with settlements, damages and other losses. To the extent adverse verdicts have been rendered against the Company, the Company does not record an accrual until a loss is determined to be probable and can be reasonably estimated. Product liability accruals can represent projected product liability for thousands of claims around the world, each in different litigation environments and with different fact patterns. Changes to the accruals may be required in the future as additional information becomes available.

* * *

Claims for personal injury have been made against Johnson & Johnson Consumer Inc. and Johnson & Johnson arising out of the use of JOHNSON'S® Baby Powder. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Lawsuits have been primarily filed in state courts in Missouri, New Jersey and California. In addition, a federal multi-district litigation proceeding has been created for this litigation in the District Court of New Jersey. The Company has established an accrual for defense costs

in connection with product liability litigation associated with JOHNSON'S® Baby Powder. Changes to this accrual may be required in the future as additional information becomes available.

327. The Company's 2016 10-K also stated that J&J "remain[ed]" committed" to "delivering high quality" and "improving existing products":

Research and development expenditures relate to the processes of discovering, testing and developing new products, *improving existing products*, as well as demonstrating product efficacy and regulatory compliance prior to launch. *The Company remains committed to investing in research and development with the aim of delivering high quality* and innovative products.

328. Defendants' statements, as alleged in ¶¶324-327, were false and misleading. While defendants boasted of "improving existing products," being "committed to investing in research and development with the aim of delivering high quality . . . products," and of J&J having "substantial defenses," they omitted that: (i) asbestos had repeatedly been found in the Company's talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67, 230), and (iv) J&J had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation (¶¶61-62, 68-72, 78, 80, 82-86, 93-104, 150-154, 223, 227, 231-232).

S. May 2017 False and Misleading Statements

329. On May 8, 2017, J&J filed its first quarter of 2017 Form 10-Q with the SEC. Defendants disclosed that J&J and some of its subsidiaries were involved in product liability litigation, but also represented that the Company had “substantial defenses”:

Johnson & Johnson and certain of its subsidiaries are involved in numerous product liability claims and lawsuits involving multiple products. Claimants in these cases seek substantial compensatory and, where available, punitive damages. While *the Company believes it has substantial defenses*, it is not feasible to predict the ultimate outcome of litigation. The Company has established accruals for product liability claims and lawsuits in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. The Company accrues an estimate of the legal defense costs needed to defend each matter when those costs are probable and can be reasonably estimated. For certain of these matters, the Company has accrued additional amounts such as estimated costs associated with settlements, damages and other losses. To the extent adverse verdicts have been rendered against the Company, the Company does not record an accrual until a loss is determined to be probable and can be reasonably estimated. Product liability accruals can represent projected product liability for thousands of claims around the world, each in different litigation environments and with different fact patterns. Changes to the accruals may be required in the future as additional information becomes available.

* * *

Claims for personal injury have been made against Johnson & Johnson Consumer Inc. and Johnson & Johnson arising out of the use of JOHNSON’S® Baby Powder. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Lawsuits have been primarily filed in state courts in Missouri, New Jersey and California. Cases filed in federal courts in the United

States have been organized as a multi-district litigation in the United States District Court for the District of New Jersey. The Company has established an accrual for defense costs in connection with product liability litigation associated with JOHNSON'S® Baby Powder.

330. Defendants' statements, as alleged in ¶329, were false and misleading. While defendants boasted of having "substantial defenses" to talc-related litigation, they omitted that: (i) asbestos had repeatedly been found in the Company's talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67, 230), and (iv) J&J had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation (¶¶61-62, 68-72, 78, 80, 82-86, 93-104, 150-154, 223, 227, 231-232).

T. August 2017 False and Misleading Statements

331. On August 24, 2017, *The Star* newspaper published an article, "Does talcum powder cause cancer and should you stop using it?" The article quoted J&J's website:

In a post on their website Johnson & Johnson said, "We do understand your concern linked to recent media reports. We want to assure you, however, that we have no higher responsibility than the health and safety of consumers and *the safety of cosmetic talc is supported by decades of scientific evidence.*"

"Since the early 1990s, many research papers and epidemiology studies have evaluated talc and perineal use and these studies have found talc to be safe.

“In fact, the Nurses’ Health Study (2010) and the Women’s Health Initiative Observational Cohort (2014), the only two large-scale prospective studies looking at talc and ovarian cancer, found no causal relationship between talc and ovarian cancer.”

332. Defendants’ representation, as alleged in ¶331 that “the safety of cosmetic talc is supported by decades of scientific evidence” was false and misleading, as it omitted that J&J knew that some scientific sources were “not as definitive or supportive and could be interpreted as suggesting a causal effect” between ovarian cancer and talc and that “[e]ven some of the studies we cite send mixed messages.” ¶¶131 and 225. And as alleged in ¶¶131 and 225, J&J knew that one of the studies it cited had determined that “perineal talc use may modestly increase the risk of invasive serous ovarian cancers.” In addition, the statements were false and misleading because they omitted that: (i) asbestos had repeatedly been found in the Company’s talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67, 230), (iv) J&J had purposely influenced and manipulated regulators and scientists in order to protect the Company’s flagship product and reputation (¶¶61-62, 68-72, 78, 80, 82-86, 93-104, 150-154, 223, 227, 231-232), and (v) J&J had misled the FDA in 2016 (¶¶150-154).

333. On August 3, 2017, J&J filed its second quarter of 2017 Form 10-Q with the SEC. Defendants disclosed that J&J and some of J&J’s subsidiaries were involved

in product liability litigation, but also represented that the Company had “substantial defenses”:

Johnson & Johnson and certain of its subsidiaries are involved in numerous product liability claims and lawsuits involving multiple products. Claimants in these cases seek substantial compensatory and, where available, punitive damages. While *the Company believes it has substantial defenses*, it is not feasible to predict the ultimate outcome of litigation. The Company has established accruals for product liability claims and lawsuits in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. The Company accrues an estimate of the legal defense costs needed to defend each matter when those costs are probable and can be reasonably estimated. For certain of these matters, the Company has accrued additional amounts such as estimated costs associated with settlements, damages and other losses. To the extent adverse verdicts have been rendered against the Company, the Company does not record an accrual until a loss is determined to be probable and can be reasonably estimated. Product liability accruals can represent projected product liability for thousands of claims around the world, each in different litigation environments and with different fact patterns. Changes to the accruals may be required in the future as additional information becomes available.

* * *

Claims for personal injury have been made against Johnson & Johnson Consumer Inc. and Johnson & Johnson arising out of the use of body powders containing talc, primarily JOHNSONS® Baby Powder. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Lawsuits have been primarily filed in state courts in Missouri, New Jersey and California. Cases filed in federal courts in the United States have been organized as a multidistrict litigation in the United States District Court for the District of New Jersey. The Company has established an accrual for defense costs in connection with product liability litigation associated with body powders containing talc.

334. Defendants' statements, as alleged in ¶333, were false and misleading. While defendants boasted of having "substantial defenses" to talc-related litigation, they omitted that: (i) asbestos had repeatedly been found in the Company's talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 288), (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67, 230), and (iv) J&J had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation (¶¶61-62, 68-72, 78, 80, 82-86, 93-104, 150-154, 223, 227, 231-232).

U. September to November 2017 False and Misleading Statements

335. On September 6, 2017, defendant Gorsky addressed the talc litigation at a Wells Fargo Healthcare Conference. There, Gorsky assured investors that J&J always puts safety first and that the safety of talc was clearly demonstrated by clinical information, control data, and "100 years of experience":

[W]e always put patient and consumer safety first in everything that we do. That being said, we think that the significant amount of clinical information, control data in this category, both from agencies, such as the NCI as well as the FDA, clearly demonstrates the safety of talc, and by the way, from more than a 100 years of experience. That being said, we were disappointed with some of the early results, for example, in St. Louis. We're encouraged by some of the recent rulings out of Supreme Court regarding those venues. We've also been encouraged by some of the earlier findings in New Jersey. We were disappointed with the first outcome in California but, nonetheless, we feel that we have some

strong ground on the field going forward. And again, we remain, based upon the data, confident of the position that we're taking.

336. Defendants' representation, as alleged in ¶335, that "the safety of talc" was "clearly demonstrate[d]" by "more than a 100 years of experience," was false and misleading. In truth, as alleged in ¶¶128 and 224, defendant J&J acknowledged internally that its talcum powders had not been "safe" for more than 100 years, and indeed, J&J could not even "link cosmetic talc to 100 years of use." The statements also created the impression that J&J's talc has historically been safe, when in fact J&J knew that when it came to asbestos in the Company's talcum powders, it could not say it was "always" asbestos-free. ¶¶128 and 224. This statement was also false and misleading because: (i) asbestos had repeatedly been found in the Company's talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), and (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67, 230).

337. Defendants' representations, as alleged in ¶335, that: (i) "the safety of talc" was "clearly demonstrate[d]" by "the significant amount of clinical information [and] control data in this category," including from the FDA, (ii) J&J "always put[s] patient and consumer safety first in everything that [it does]," and (iii) J&J believed it "ha[d] some strong ground on the field going forward" in the talc litigation and "remain[ed], based upon the data, confident of the position [it was] taking," were false and misleading. These statements concealed that: (i) asbestos had repeatedly been

found in the Company's talc and powders (§§55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (§§58, 60, 228), (iii) J&J never adopted concentration methods that could detect the asbestos (§§63-67, 230), (iv) J&J had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation (§§61-62, 68-72, 78, 80, 82-86, 93-104, 150-154, 223, 227, 231-232), and (v) J&J had misled the FDA in 2016 (§§150-154).

338. On September 14, 2017, a *Bloomberg* article entitled "Johnson & Johnson's Newest Talc Problem? Asbestos" quoted J&J's website:

Johnson & Johnson declined to comment either on Herford's suit or the litigation generally. But a statement on the company's website says: "Since the 1970s, *talc used in consumer products has been required to be asbestos-free*, so *Johnson's talc products do not contain asbestos*."

339. On September 21, 2017, *Bloomberg* published an article titled "J&J Was Alerted to Risk of Asbestos in Talc in '70s, Files Show," which cited additional statements from J&J:

FDA Requirements

"The U.S. Food and Drug Administration requires specific testing to ensure that cosmetic talcum powder is free of asbestos," Ernie Knewitz, a spokesman for J&J, said in an emailed statement.

"*We are confident that our talc products are, and always have been, free of asbestos, based on decades of monitoring, testing and regulation*," Knewitz said. "Historical testing of samples by the FDA, numerous independent laboratories, and numerous independent scientists have all confirmed the absence of asbestos in our talc products."

* * *

New Brunswick, New Jersey-based ***J&J has said the plaintiffs' allegations aren't supported by valid scientific evidence***, pointing to a New Jersey state court decision last year tossing out two cases.

The unsealed files were used as part of an April pre-trial deposition given by Joanne Waldstreicher <<https://www.jnj.com/office-chief-medical-officer>>, J&J's chief medical officer since 2013. Under questioning by plaintiffs' lawyer Mark Lanier, ***Waldstreicher maintained that J&J's baby powder products are asbestos free. We have experts that assure there's no asbestos in our talc,*** she told the lawyer.

340. On November 16, 2017, *Law360* published an article entitled "J&J, Talc Supplier Not Liable For Woman's Asbestos Illness," citing statements by J&J:

J&J spokesperson Carol Goodrich told *Law360* on Thursday that the company stands behind the safety of its baby powder, which it believes is being vindicated in recent court decisions.

"We are pleased with today's verdict and believe that the dismissal of talc lawsuits in New Jersey and verdict reversals in Missouri and California have forced plaintiff attorneys to pivot to yet ***another baseless theory***," she said. ***"Johnson's Baby Powder has been around since 1894 and it does not contain asbestos or cause mesothelioma or ovarian cancer."***

341. Also on November 16, 2017, *Reuters* published a statement by J&J in the article entitled "Johnson & Johnson wins California lawsuit claiming asbestos in talc caused cancer":

J&J in a statement welcomed the verdict. J&J said it believed that setbacks dealt to individuals pursuing ovarian cancer cases had "forced plaintiff attorneys to pivot to yet another baseless theory."

“Johnson’s Baby Powder has been around since 1894 and it does not contain asbestos or cause mesothelioma or ovarian cancer,”
J&J said.

342. Defendants’ statement, as alleged in ¶339, that J&J’s “‘talc products are, and always have been, free of asbestos,’” was false and misleading because, as alleged in ¶¶128 and 224, J&J knew internally that “we cannot say ‘always.’” Similarly, defendants’ reference to Johnson’s Baby Powder having “‘been around since 1894’” coupled with the representation that “‘it does not contain asbestos or cause mesothelioma or ovarian cancer’” created the impression that the Baby Powder had always been asbestos-free, while J&J acknowledged that “we cannot say ‘always.’” In addition, as alleged in ¶¶128 and 224, defendant Goodrich knew that the Baby Powder had not been safe for the past 100 years and even had in her possession internal discussion stating that “I don’t think we can link cosmetic talc to 100 years of use.” These statements, along with defendants’ representations that J&J’s “talc products do not contain asbestos” and that J&J’s “baby powder products are asbestos free,” were false and misleading because they concealed that (i) asbestos had repeatedly been found in the Company’s talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), and (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67, 230).

343. Defendants' statements, as alleged in ¶¶338-340, that: (i) J&J's "'experts . . . assure there's no asbestos in [its] talc,'" (ii) "the plaintiffs' allegations [weren't] supported by valid scientific evidence" and amounted to a "'baseless theory,'" (iii) "decades of monitoring, testing and regulation" assured that J&J's "'talc products are, and always have been, free of asbestos,'" and (iv) "'talc used in consumer products has been required to be asbestos-free'" "[s]ince the 1970s," were false and misleading. These statements concealed that: (i) asbestos had repeatedly been found in the Company's talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67, 230), and (iv) J&J had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation (¶¶61-62, 68-72, 78, 80, 82-86, 93-104, 150-154, 223, 227, 231-232). The statement regarding plaintiffs' allegations not being "supported by valid scientific evidence" was false and misleading for the additional reason that J&J knew that in fact some scientific sources, including IARC and the American Cancer Society, were actually "not as definitive or supportive and could be interpreted as suggesting a causal effect" between ovarian cancer and talc and that "[e]ven some of the studies [J&J] cite[d] send[s] mixed messages." ¶¶131 and 225. For example, as alleged in ¶¶131 and 225, J&J knew one

of the studies it cited had concluded that ““perineal talc use may modestly increase the risk of invasive serous ovarian cancers.””

344. On November 2, 2017, J&J filed its third quarter of 2017 Form 10-Q with the SEC. Defendants acknowledged that J&J and some of J&J’s subsidiaries were involved in product liability litigation, but also represented that the Company had “substantial defenses”:

Johnson & Johnson and certain of its subsidiaries are involved in numerous product liability claims and lawsuits involving multiple products. Claimants in these cases seek substantial compensatory and, where available, punitive damages. While *the Company believes it has substantial defenses*, it is not feasible to predict the ultimate outcome of litigation. The Company has established accruals for product liability claims and lawsuits in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. The Company accrues an estimate of the legal defense costs needed to defend each matter when those costs are probable and can be reasonably estimated. For certain of these matters, the Company has accrued additional amounts such as estimated costs associated with settlements, damages and other losses. To the extent adverse verdicts have been rendered against the Company, the Company does not record an accrual until a loss is determined to be probable and can be reasonably estimated. Product liability accruals can represent projected product liability for thousands of claims around the world, each in different litigation environments and with different fact patterns. Changes to the accruals may be required in the future as additional information becomes available.

* * *

Claims for personal injury have been made against Johnson & Johnson Consumer Inc. and Johnson & Johnson arising out of the use of body powders containing talc, primarily JOHNSONS® Baby Powder. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to

potential costs and the anticipated number of cases. Lawsuits have been primarily filed in state courts in Missouri, New Jersey and California. Cases filed in federal courts in the United States have been organized as a multidistrict litigation in the United States District Court for the District of New Jersey. The Company has established an accrual for defense costs in connection with product liability litigation associated with body powders containing talc.

345. Defendants' statements, as alleged in ¶344, were false and misleading. While defendants boasted of having "substantial defenses" to the talc-related litigation, they omitted that: (i) asbestos had repeatedly been found in the Company's talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67, 230), and (iv) J&J had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation (¶¶61-62, 68-72, 78, 80, 82-86, 93-104, 150-154, 223, 227, 231-232).

V. January 2018 False and Misleading Statements

346. On January 16, 2018, *Fair Warning* published a story entitled "Baby Powder Battles: Johnson & Johnson Internal Documents Reveal Asbestos Worries." *Fair Warning* reported that *J&J* "***has said its powders are perfectly safe, and could not have caused mesothelioma.***"

347. *Fair Warning* also reported additional false and misleading statements made by J&J:

Reports of asbestos contamination have “never been proven to be correct,” declared John Hopkins, a toxicologist and former J&J executive.

Defense lawyers made a plausible case for a different cause of Herford’s mesothelioma: the aggressive radiation treatments she received for breast cancer in 1998. Therapeutic radiation is one of the only suspected causes of mesothelioma other than asbestos.

Following its victory, ***J&J blasted the “baseless theory” that its powders could be harmful. “Johnson’s Baby Powder has been around since 1894 and it does not contain asbestos or cause mesothelioma,”*** according to the company’s statement.

348. Defendants’ statements, as alleged in ¶347, that Johnson’s Baby Powder has ““been around since 1894”” and that ““it does not contain asbestos or cause mesothelioma,”” were false and misleading, creating the false impression that the Baby Powder had always been asbestos-free, while the Company recognized internally that it could not say ““always.”” ¶¶128 and 224. This statement was also false and misleading because it concealed that: (i) asbestos had repeatedly been found in the Company’s talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), and (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67, 230).

349. Similarly, defendants’ representations, as alleged in ¶¶346-347, that it was a ““baseless theory”” that the Company’s products could be harmful, that reports of asbestos contamination ““have ““never been proven to be correct,””“ and that J&J’s ““powders are perfectly safe, and could not have caused mesothelioma,”” were false and

misleading. These statements concealed that: (i) asbestos had repeatedly been found in the Company's talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67, 230), and (iv) J&J had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation (¶¶61-62, 68-72, 78, 80, 82-86, 93-104, 150-154, 223, 227, 231-232).

W. February to April 2018 False and Misleading Statements

350. On February 5, 2018, in an article entitled "Johnson & Johnson falls on report that lawsuits could expose potentially damaging documents," CNBC quoted a J&J spokesman:

In a statement, a J&J spokesman pointed to a California judge ruling in favor of J&J in November in a lawsuit by a woman who said she developed mesothelioma after using the company's talc-based products. He said the company would continue to defend its position in future cases.

"We are confident that our talc products are, and always have been, free of asbestos, based on decades of monitoring, testing and regulation dating back to the 1970s," he said. "Historical testing of samples by the FDA, numerous independent laboratories, and numerous independent scientists have all confirmed the absence of asbestos in our talc products."

351. Defendants' statement, as alleged in ¶350, that J&J's "'talc products are, and always have been, free of asbestos,'" was false and misleading because, as alleged in ¶¶128 and 224, J&J knew internally that it could not "say 'always.'" This

statement, along with defendants' representation, as alleged in ¶350, that "decades of monitoring [and] testing" "dating back to the 1970s" supported the notion that the products have "always . . . been . . . free of asbestos," were false and misleading because they concealed that (i) asbestos had repeatedly been found in the Company's talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), and (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67, 230).

352. Defendants' statements, as alleged in ¶350, that: (i) "the absence of asbestos in our talc products" had been "confirmed" by "[h]istorical testing of samples by the FDA, numerous independent laboratories, and numerous independent scientists," and (ii) "decades of . . . regulation dating back to the 1970s" assured that J&J's "talc products are, and always have been, free of asbestos" were also false and misleading. These statements concealed that: (i) asbestos had repeatedly been found in the Company's talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67, 230), (iv) J&J had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation (¶¶61-62, 68-72, 78, 80, 82-86, 93-104, 150-154, 223, 227, 231-232), and (v) J&J had misled the FDA in 2016 (¶¶150-154).

353. On February 21, 2018, J&J filed its 2017 10-K with the SEC, signed by defendants Gorsky and Caruso (“2017 10-K”). In its “Cautionary Note Regarding Forward-Looking Statements,” J&J included language regarding “[p]roduct efficacy or safety concerns”:

Risks Related to Product Liability, Litigation and Regulatory Activity

- Product efficacy or safety concerns, whether or not based on scientific evidence, potentially resulting in product withdrawals, recalls, regulatory action on the part of the U.S. Food and Drug Administration (or international counterparts), declining sales and reputational damage.

354. The Company’s 2017 10-K also discussed the general risks and uncertainties faced by the Company, including legal proceedings:

The Company is subject to significant legal proceedings that can result in significant expenses, fines and reputational damage.

In the ordinary course of business, Johnson & Johnson and its subsidiaries are subject to numerous claims and lawsuits involving various issues such as patent disputes, product liability and claims that their product sales, marketing and pricing practices violate various antitrust, unfair trade practices and/or consumer protection laws. The most significant of these proceedings are described in Note 21, “Legal Proceedings” under Notes to the Consolidated Financial Statements included in Item 8 of this Report. While ***the Company believes it has substantial defenses in these matters***, it is not feasible to predict the ultimate outcome of litigation. The Company could in the future be required to pay significant amounts as a result of settlements or judgments in these matters, potentially in excess of accruals. The resolution of, or increase in accruals for, one or more of these matters in any reporting period could have a material adverse effect on the Company’s results of operations and cash flows for that period. Furthermore, as a result of cost and availability factors, effective

November 1, 2005, the Company ceased purchasing third-party product liability insurance.

Product reliability, safety and effectiveness concerns can have significant negative impacts on sales and results of operations, lead to litigation and cause reputational damage.

Concerns about product safety, whether raised internally or by litigants, regulators or consumer advocates, and whether or not based on scientific evidence, can result in safety alerts, product recalls, governmental investigations, regulatory action on the part of the FDA (or its counterpart in other countries), private claims and lawsuits, payment of fines and settlements, declining sales and reputational damage. These circumstances can also result in damage to brand image, brand equity and consumer trust in the Company's products. Product recalls have in the past, and could in the future, prompt government investigations and inspections, the shutdown of manufacturing facilities, continued product shortages and related sales declines, significant remediation costs, reputational damage, possible civil penalties and criminal prosecution.

355. J&J's 2017 10-K acknowledged that the Company and some of its subsidiaries were involved in product liability litigation, but also represented that J&J had "substantial defenses":

Johnson & Johnson and certain of its subsidiaries are involved in numerous product liability claims and lawsuits involving multiple products. Claimants in these cases seek substantial compensatory and, where available, punitive damages. While *the Company believes it has substantial defenses*, it is not feasible to predict the ultimate outcome of litigation. The Company has established accruals for product liability claims and lawsuits in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. The Company accrues an estimate of the legal defense costs needed to defend each matter when those costs are probable and can be reasonably estimated. For certain of these matters, the Company has accrued additional amounts such as estimated costs associated with settlements, damages and other losses. To the extent adverse verdicts have been rendered against the Company, the Company does not record an accrual until a loss is determined to be probable and can be reasonably

estimated. Product liability accruals can represent projected product liability for thousands of claims around the world, each in different litigation environments and with different fact patterns. Changes to the accruals may be required in the future as additional information becomes available.

* * *

Claims for personal injury have been made against Johnson & Johnson Consumer Inc. and Johnson & Johnson arising out of the use of body powders containing talc, primarily JOHNSONS® Baby Powder. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Lawsuits have been primarily filed in state courts in Missouri, New Jersey and California. Cases filed in federal courts in the United States have been organized as a multidistrict litigation in the United States District Court for the District of New Jersey. The Company has established an accrual for defense costs in connection with product liability litigation associated with body powders containing talc.

356. The Company's 2017 10-K also stated that J&J "remain[ed]" committed to "delivering high quality" and "improving existing products":

Research and development expenditures relate to the processes of discovering, testing and developing new products, upfront payments and milestones, *improving existing products*, as well as demonstrating product efficacy and regulatory compliance prior to launch. *The Company remains committed to investing in research and development with the aim of delivering high quality* and innovative products.

357. Defendants' statements, as alleged in ¶¶353-356, were false and misleading. While defendants boasted of "improving existing products," being "committed to investing in research and development with the aim of delivering high quality . . . products," and of J&J having "substantial defenses," they omitted that: (i) asbestos had repeatedly been found in the Company's talc and powders (¶¶55-57, 59,

64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67, 230), and (iv) J&J had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation (¶¶61-62, 68-72, 78, 80, 82-86, 93-104, 150-154, 223, 227, 231-232).

358. On February 26, 2018, at the Committee Encouraging Corporate Philanthropy CEO Investor Forum, defendant Gorsky told investors:

I think the real special sauce at Johnson & Johnson is our credo. And to think that, that document – and, again, this thing was written more than 75 years ago. In fact, this is the 75th anniversary of ***Our Credo***. Long before corporate social responsibility was in the day-to-day lexicon or vernacular, and the fact that the son of our founder took the time to write this out in such an eloquent way, a little over 300 words, talking about commitments, I think it's just incredibly inspiring. And ***it's really formed kind of the value system, the backdrop and in fact, I'd say the strategy outline for Johnson & Johnson in everything we do.***

359. On April 12, 2018, the *New York Daily News* reported on statements made by defendant Goodrich, in response to the Lanzo trial verdict:

J&J denied that its products contain cancer-causing toxins and says it plans to appeal.

“Johnson's Baby Powder has been used for more than 120 years and it does not contain asbestos or cause mesothelioma,” said spokeswoman Carol Goodrich. ***“We believe that once the full evidence is reviewed, this decision will be reversed.”***

360. Then, on April 26, 2018, at J&J's Annual Shareholders Meeting, defendant Gorsky told investors:

And Our Credo, it dates back to 1943, authored by the then Chairman Robert Wood Johnson II, the son of one of the founding Johnson brothers. And it was right before Johnson & Johnson became a public company. And on that day, at that moment, Johnson & Johnson's moral compass as a family, as a company, was formally documented, and that has sustained us for these past 75 years.

Our Credo, well, *it stood the test of time*, unyielding in challenging times and unforgotten in times of great success. It balances opportunity with responsibility. And *we are united and inspired by Our Credo, and we live into those responsibilities it outlines each and every day*. It reminds us that our very first responsibility is to customers and patients. And it compels us to deliver on our responsibilities to our employees, our communities, our environment and to you, our shareholders. And it's because of our strong credo foundation and being broadly based in health care that we are committed to profoundly changing the trajectory of health for humanity.

To accomplish this, we intend to: first, invest in areas for enduring long-term impact; position our businesses to deliver strong, consistent and sustainable results; lead with agility and a sense of urgency needed to tackle the world's changing needs; to create life-enhancing innovations, all while empowering and inspiring diverse employees and an inclusive culture; and continue to use our reach and size for good. Now through the many decades of change that we've seen in the health care industry's experience, *Johnson & Johnson has continued to advance with the evolution of science and technology*, whether it was through our pioneering development of sterile surgery at the turn of the 20th century or today, as we develop a differentiated robotic-assisted surgery platform in orthopaedics [sic] or build novel regimens to boost T cells and train them to recognize and actually attack cancer and focus to create a preventive vaccine for HIV/AIDS.

361. At the April 26, 2018 Shareholders Meeting, Gorsky also told investors:

Now at Johnson & Johnson, we are committed to meeting the needs of our stakeholders, as defined in Our Credo, the doctors, the nurses and patients and the mothers and fathers and all others who use our products; our employers, our suppliers, and the communities in which we live and work. We're also committed to providing positive

economic impact wherever we do business as well as delivering a fair return to our shareholders.

Now our people and our partners have been focused on that one thing, the thing that is the most important, the most personal to every individual and every family on earth: their health and well-being. And for the second year in a row, we were named to the annual Fortune Magazine Change the World List, which spotlights the 50 top global companies that have had a positive social impact through their activities that are part of their core business strategy.

* * *

We recognize that to lead the next frontier of health, well, it's a big commitment. But we are ready, willing and able to take on this task. ***Guided by our purpose-driven strategies and values that are rooted in our credo, we will always put the needs and well-being of the people we serve first.***

362. Defendants' statements, as alleged in ¶¶358, 360-361, that (i) its Credo was "the value system, the backdrop and in fact . . . the strategy outline for Johnson & Johnson in everything" it does, (ii) its Credo "stood the test of time, unyielding in challenging times and unforgotten in times of great success," (iii) J&J is "united and inspired by Our Credo, and we live into those responsibilities it outlines each and every day," (iv) J&J is "committed to meeting the needs of our stakeholders, as defined in Our Credo, the doctors, the nurses and patients and the mothers and fathers and all others who use our products," (v) J&J has "been focused on that one thing, the thing that is the most important, the most personal to every individual and every family on earth: their health and well-being," and (vi) J&J "will always put the needs and well-being of the people we serve first," were false and misleading. In truth,

defendants had and continued to conceal that: (i) asbestos had repeatedly been found in the Company's talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67, 230), (iv) J&J had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation (¶¶61-62, 68-72, 78, 80, 82-86, 93-104, 150-154, 223, 227, 231-232), and (v) J&J had misled the FDA in 2016 (¶¶150-154).

363. Defendant Goodrich's statements, as alleged in ¶359, that (i) "Johnson's Baby Powder has been used for more than 120 years and it does not contain asbestos or cause mesothelioma," and (ii) "once the full evidence is reviewed, [the Lanzo verdict] will be reversed," were false and misleading. In truth, as alleged in ¶¶128 and 224, Goodrich knew that J&J's talcum powders had not been "safe" for over 100 years, and indeed, J&J could not even "link cosmetic talc to 100 years of use." Goodrich also knew that when it came to asbestos in the Company's talcum powders, they could not "say 'always'" asbestos free. ¶¶128 and 224. These statements were false and misleading because they omitted that: (i) asbestos had repeatedly been found in the Company's talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67,

230), and (iv) J&J had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation (§§61-62, 68-72, 78, 80, 82-86, 93-104, 150-154, 223, 227, 231-232).

364. Defendant Gorsky's statement, as alleged in ¶360, that J&J "has continued to advance with the evolution of science and technology" was false and misleading because it concealed that J&J: (i) never adopted concentration methods that could detect the asbestos in J&J's talcum powders (§§63-67, 230), and (ii) continued to sell its talcum powders despite knowing that asbestos had repeatedly been found in the Company's talc and powders (§§55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228).

X. May 2018 False and Misleading Statements

365. On May 1, 2018, J&J filed its Form 10-Q with the SEC for the first quarter of 2018. Defendants disclosed that J&J and some of J&J's subsidiaries were involved in product liability litigation, but also represented that the Company had "substantial defenses":

Johnson & Johnson and certain of its subsidiaries are involved in numerous product liability claims and lawsuits involving multiple products. Claimants in these cases seek substantial compensatory and, where available, punitive damages. While *the Company believes it has substantial defenses*, it is not feasible to predict the ultimate outcome of litigation. The Company has established accruals for product liability claims and lawsuits in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. The Company accrues an estimate of the legal defense costs needed to defend each matter when those costs are probable and can be reasonably

estimated. For certain of these matters, the Company has accrued additional amounts such as estimated costs associated with settlements, damages and other losses. To the extent adverse verdicts have been rendered against the Company, the Company does not record an accrual until a loss is determined to be probable and can be reasonably estimated. Product liability accruals can represent projected product liability for thousands of claims around the world, each in different litigation environments and with different fact patterns. Changes to the accruals may be required in the future as additional information becomes available.

* * *

Claims for personal injury have been made against Johnson & Johnson Consumer Inc. and Johnson & Johnson arising out of the use of body powders containing talc, primarily JOHNSONS® Baby Powder. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Lawsuits have been primarily filed in state courts in Missouri, New Jersey and California. Cases filed in federal courts in the United States have been organized as a multidistrict litigation in the United States District Court for the District of New Jersey. The Company has established an accrual for defense costs only in connection with product liability litigation associated with body powders containing talc.

366. Defendants' statements, as alleged in ¶365, were false and misleading.

While defendants boasted of having "substantial defenses" to talc-related litigation, they omitted that: (i) asbestos had repeatedly been found in the Company's talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67, 230), and (iv) J&J had purposely influenced and manipulated regulators and scientists in order to protect the

Company's flagship product and reputation (¶¶61-62, 68-72, 78, 80, 82-86, 93-104, 150-154, 223, 227, 231-232).

367. On May 16, 2018, CNBC published a video interview with defendant Gorsky regarding the re-launch of J&J's Baby Products line. In the interview, defendant Gorsky made the following statements:

[Gorsky:] [I]t's a re-launch, and we're really focusing on . . . the changing needs of the Millennial mom, and we realize that over the past few years that we probably got a little bit behind the curve, but what you're going to hear about today is how we totally reformulated the brand where we're changing and making sure we're using more natural ingredients. ***We've taken out many of the concerning products, or ingredients, that . . . mothers didn't want in their products***, things like surfactants, parabens, and other . . . ingredients. And we've also made sure that we're really creating a conversation with the Millennial mom. So yeah, ***we're really excited about the re-launch of Baby, and we think what it does is it makes it current***, it makes it relevant, but at the same time it doesn't lose . . . that basic smell, that basic touch that you expect from the Johnson's Baby line.

[Reporter:] Well this comes after a couple years you've had some . . . pretty extreme headlines coming out of the lawsuits around the talc baby powder product. You know, I've heard from some folks they've lost trust in the brand because of those headlines that they're seeing and the concerns of some link to cancer from the talc baby products. . . . I talked with Jorge Mesquita, your Head of Consumer, who said you defend the brand, the science shows there is no link to cancer and that wasn't the driver behind the re-launch. But how do you keep consumers' trust, perhaps win back their trust, in the midst of all these headlines?

[Gorsky:] Well look, we certainly understand that. And ***when it comes to babies, safety, high quality has got to be first and foremost in everything that we do***. And so what we're talking about today is how do we take these legacy brands and really better position them for the future. You know, for example, ***let's start with clinical data and***

information. You know, J&J, we have conducted more than 90% of the clinical trials. And the Millennial mom, they have a high expectation about data. *They want to know, frankly, do these products work. Are they safe and are they effective. And the fact that we are able to produce that kind of information behind our brands, that we share it with the broader community, is really important.* So those are some of the steps that we're taking . . . we think to make sure the brands do well today but also into the future.

368. On May 16, 2018, at the Consumer and Medical Devices Business Review, defendant Gorsky told investors:

So now what I'd like to do is take just a few moments to highlight the strengths and the opportunities for each of our different business segments. . . .

And look, *we're not afraid to acknowledge areas that we need to fix. We want to talk about that, learn from them to make us better going forward.* And we firmly believe that Johnson & Johnson is strongly positioned for continued and future growth.

* * *

So in closing, first and foremost, I want to thank you for being here today and investing your time in Johnson & Johnson. . . .

And *you've got our absolute commitment that we'll hold ourselves accountable and* execute on the strategic plans that you're going to hear about today, *fulfill all of our Credo responsibilities where we always keep the customer and patients at the center of everything we do* and ultimately profoundly change the trajectory of health for humanity.

369. Also at the May 16, 2018, Consumer and Medical Devices Business Review, Global Chief Technology Officer Josh Ghaim told investors:

We have designed JOHNSON'S with everything a mom wants for 100% gentle new classics. *While our ingredients have been always been safe, our new formulations contain no unwanted ingredients.* To

meet the needs of new moms today, more than 90% of the ingredients in our formulations are natural. We have built superior experience with no-residue formulas, professional reassurance through dermatologist and pediatrician testing, all with unique claims based on our body of baby skin science.

370. And at the same May 16, 2018 Conference, Executive VP and Worldwide Chairman Jorge Mesquita responded to a question from an analyst regarding talc:

With regard to talc, sorry. What I can assure you is ***we’ve been through this extensively, and we are 100% sure that our talc product is safe.*** And we will continue to defend our brand, we will continue to defend our product.

371. Defendants’ statements, as alleged in ¶¶367-368, that: (i) “when it comes to babies” safety and high quality are “first and foremost in everything that we do,” (ii), J&J is “not afraid to acknowledge areas that [it] need[s] to fix” and J&J “want[s] to talk about that” and “learn from them to make [itself] better going forward,” and (iii) J&J “hold[s] [itself] accountable” on “fullfill[ing] all of our Credo responsibilities where we always keep the customer and patients at the center of everything we do,” were false and misleading. Rather than putting safety first, acknowledging and learning from its mistakes, or holding themselves accountable to J&J’s Credo, defendants continued to conceal the truth regarding its Baby Powder, including that: (i) asbestos had repeatedly been found in the Company’s talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), (iii) J&J never adopted concentration

methods that could detect the asbestos (§§63-67, 230), (iv) J&J had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation (§§61-62, 68-72, 78, 80, 82-86, 93-104, 150-154, 223, 227, 231-232), and (v) J&J had misled the FDA in 2016 (§§150-154).

372. Defendants' statement, as alleged in §369, that J&J's ingredients "have . . . always been safe," was false and misleading, as J&J acknowledged internally that "we cannot say 'always'" with regards to J&J's talcum powders being asbestos-free. This statement, along with the statements alleged in §§367 and 369, that: (i) J&J had "taken out many of the concerning . . . ingredients, that . . . mothers didn't want in their products," (ii) "the re-launch of Baby" makes the product line "current," (iii) J&J's large number of clinical trials show that the Baby products are safe, and (iv) J&J's "new formulations contain no unwanted ingredients," were false and misleading for other reasons. These statements concealed that: (i) asbestos had repeatedly been found in the Company's talc and powders (§§55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (§§58, 60, 228), and (iii) J&J never adopted concentration methods that could detect the asbestos (§§63-67, 230).

373. Defendants' statement, as alleged in §370, that after going through the information "extensively," J&J is "100% sure that our talc product is safe," was also false and misleading. In truth, J&J knew that some scientific sources were actually

“not as definitive or supportive and could be interpreted as suggesting a causal effect” between ovarian cancer and talc and that “[e]ven some of the studies [it] cite[d] send[s] mixed messages.” ¶¶131 and 225. And as alleged in ¶¶131 and 225, J&J knew that even one of the studies cited by J&J had concluded that ““perineal talc use may modestly increase the risk of invasive serous ovarian cancers.”” In addition, the statement was false and misleading because it failed to disclose that: (i) asbestos had repeatedly been found in the Company’s talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67, 230), and (iv) J&J had purposely influenced and manipulated regulators and scientists in order to protect the Company’s flagship product and reputation (¶¶61-62, 68-72, 78, 80, 82-86, 93-104, 150-154, 223, 227, 231-232).

374. On May 21, 2018, at the UBS Global Healthcare Conference, defendant Peterson discussed J&J’s global supply chain:

We did make an announcement that we’re taking some actions to further optimize our network and I’ll explain to you why that is. But about 5 years ago, we had changed our approach at JNJ to how we manage our supply chain around the globe to enable us to have much more global consistency, to drive better flexibility in our supply chain, but also to ensure that *we’ve got the right quality and compliance in all of our manufacturing sites around the world, both internal and external.*

375. Also on May 21, 2018, in an article entitled “Johnson & Johnson to relaunch baby-care line after its 20% sales decline,” Mesquita was quoted as stating: “***We are absolutely certain that science shows that our talcum product is safe,*** and we will defend our brand and defend our product,’ Mesquita said.”

376. And on May 28, 2018, in an article entitled “Juries Weigh Cases Over Alleged Harms of Johnson & Johnson Baby Powder,” the *Wall Street Journal* reported statements made by J&J:

Johnson & Johnson said it would appeal and “continue to defend the safety of our product because ***it does not contain asbestos or cause mesothelioma.***” The company said ***over the past 50 years, multiple scientific evaluations, including from the U.S. Food and Drug Administration, have been conducted and “none have found that the talc in Johnson’s Baby Powder contains asbestos.”***

377. Defendants’ statement, as alleged in ¶374, that J&J now had “the right quality and compliance in all of [its] manufacturing sites around the world,” was false and misleading, as J&J had knowingly failed to adopt an effective method for testing its talc (¶¶63-67, 230), despite numerous occasions of asbestos being found in the Company’s talc and powders. ¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228.

378. Defendants’ statements, as alleged in ¶¶375-376, that: (i) J&J is “absolutely certain that science shows that our talcum product is safe,” and (ii) Johnson’s Baby Powder ““does not contain asbestos or cause mesothelioma,”” as ““multiple scientific evaluations”” ““over the past 50 years”” including by the FDA have not found asbestos in Johnson’s Baby Powder, were also false and misleading.

These statements concealed that: (i) asbestos had repeatedly been found in the Company's talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67, 230), (iv) J&J had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation (¶¶61-62, 68-72, 78, 80, 82-86, 93-104, 150-154, 223, 227, 231-232), and (v) J&J had misled the FDA in 2016 (¶¶150-154). In addition, while J&J said publicly that it was “absolutely certain that science shows” the safety of talc, it knew that some scientific sources were actually “not as definitive or supportive and could be interpreted as suggesting a causal effect” between ovarian cancer and talc and that at least one had concluded that “perineal talc use may modestly increase the risk of invasive serous ovarian cancers.” ¶¶131 and 225.

Y. July to August 2018 False and Misleading Statements

379. On July 12, 2018, J&J issued a statement regarding the Ingham case verdict:

Johnson & Johnson is deeply disappointed in *the verdict, which was the product of a fundamentally unfair process* that allowed plaintiffs to present a group of 22 women, most of whom had no connection to Missouri, in a single case all alleging that they developed ovarian cancer. The result of the verdict, which awarded the exact same amounts to all plaintiffs irrespective of their individual facts, and differences in applicable law, reflects that *the evidence in the case was simply overwhelmed by the prejudice* of this type of proceeding.

Johnson & Johnson remains confident that its products do not contain asbestos and do not cause ovarian cancer and intends to pursue all available appellate remedies. ***Every verdict against Johnson & Johnson in this court that has gone through the appeals process has been reversed and the multiple errors present in this trial were worse than those in the prior trials which have been reversed.***

380. Also on July 12, 2018, *Bloomberg* reported on comments made by defendant Goodrich via email³¹:

The company will appeal, Carol Goodrich, a spokeswoman, said in an email. The verdict “***was the product of a fundamentally unfair process*** that allowed plaintiffs to present a group of 22 women, most of whom had no connection to Missouri, in a single case all alleging that they developed ovarian cancer,” she said.

That each plaintiff and her family members were awarded \$25 million for their losses “irrespective of their individual facts, and differences in applicable law, reflects that ***the evidence in the case was simply overwhelmed by the prejudice*** of this type of proceeding,” Goodrich added.

* * *

‘Multiple Errors’

The company’s products don’t contain asbestos and don’t cause ovarian cancer, she said. Goodrich predicted the verdict would be reversed. “The multiple errors present in this trial were worse than those in the prior trials which have been reversed.”

381. Defendants’ statements, as alleged in ¶¶379-380, that the verdict was “the product of a fundamentally unfair process” where the “evidence . . . was simply overwhelmed by the prejudice,” while the truth was that J&J’s products “do not

³¹ “J&J’s \$4.69 Billion Talc Loss Hands Investors a What-Next Moment” (updated on July 13, 2018).

contain asbestos and do not cause ovarian cancer,” were false and misleading. In truth, defendants knew that: (i) asbestos had repeatedly been found in the Company’s talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67, 230), and (iv) J&J had purposely influenced and manipulated regulators and scientists in order to protect the Company’s flagship product and reputation (¶¶61-62, 68-72, 78, 80, 82-86, 93-104, 150-154, 223, 227, 231-232). In addition, Goodrich knew that the Company could not “say ‘always’” when it comes to Johnson’s Baby Powder being asbestos-free. ¶¶128 and 224. And while Goodrich promised that J&J’s talc did not cause ovarian cancer, she knew that some scientific sources were actually “not as definitive or supportive and could be interpreted as suggesting a causal effect” between ovarian cancer and talc and that at least one had concluded that “‘perineal talc use may modestly increase the risk of invasive serous ovarian cancers.’” ¶¶131 and 225.

382. On July 17, 2018, during a conference call discussing the Company’s 2Q18 results, defendant Gorsky told investors:

Before I provide some perspective by business segment, it’s important to begin where I usually do, emphasizing that ***we are always guided by our credo***; and this year, we proudly celebrate its 75th anniversary. ***Our credo is as relevant today as the day it was written.*** Balancing opportunity and responsibility, ***we’re united and inspired by***

our credo and we live in the responsibilities it outlines each and every day.

* * *

Additionally, we are revitalizing our baby business. In fact, beginning this month, our newly formulated Johnson's Baby products have started to ship to retailers across the United States. We continue to strengthen and expand our portfolio of iconic, ***science-based and professionally endorsed products***, and we have a number of planned launches in the second half of this year. We also believe that this will drive top line growth that will be met with even greater bottom line growth as we continue to improve our productivity and margins.

* * *

Regarding the recent St. Louis talcum powder lawsuit and verdict. As you know, our baby powder is a trusted product that we sold to families for over 100 years, and Johnson & Johnson is deeply disappointed in this verdict. Now ***we remain confident that our products do not contain asbestos and do not cause ovarian cancer***, and we intend to pursue all available appellate remedies. In fact, every verdict against Johnson & Johnson in this court that has gone through the appeals process has been reversed.

Additionally, I want to emphasize that ***preeminent scientific and regulatory bodies, including the National Cancer Institute, the U.S. Food and Drug Administration have fully reviewed the full body of scientific evidence on multiple occasions and found that it does not support the allegation that talc causes ovarian cancer.*** Like previous appeals, we are confident that there are multiple grounds for reversal of this jury verdict and that, ultimately, the case will be reversed.

* * *

We believe in a bright and successful future, where virtually anything that can be imagined, can be accomplished through a laser-like focus on innovation, execution and our customers, which ultimately drives superior long-term performance. And while we're focused on all of this, ***we also remain committed to fulfilling our credo responsibilities*** and striving to profoundly change the trajectory of Health for Humanity.

383. Defendants' statement, as alleged in ¶382, that J&J is "always guided by our credo," was false and misleading, as it concealed that: (i) asbestos had repeatedly been found in the Company's talc and powders but J&J failed to inform the public (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had thought about seeking a profitable patent for a method of removing tremolite from its talc (¶¶58, 60), (iii) J&J never adopted concentration methods that could detect the asbestos despite knowing that it was necessary to find any asbestos present (¶¶63-67, 230), (iv) J&J had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation (¶¶61-62, 68-72, 78, 80, 82-86, 93-104, 150-154, 223, 227, 231-232), and (v) J&J had misled the FDA in 2016 (¶¶150-154).

384. Defendants' statements, as alleged in ¶382, that: (i) J&J remained "committed to fulfilling our credo responsibilities," (ii) the Credo was "as relevant today as the day it was written," and (iii) J&J was "inspired by our credo" and "live[d] in the responsibilities it outlines each and every day," were false and misleading. In truth, defendants failed to live up to the Credo by continuing to conceal the truth about Johnson's Baby Powder, including that: (i) asbestos had repeatedly been found in the Company's talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67,

230), (iv) J&J had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation (¶¶61-62, 68-72, 78, 80, 82-86, 93-104, 150-154, 223, 227, 231-232), and (v) J&J had misled the FDA in 2016 (¶¶150-154).

385. Defendant's statement, as alleged in ¶382, that J&J had "science-based and professionally endorsed products," was false and misleading as (i) asbestos had repeatedly been found in the Company's talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228) and (ii) J&J had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation (¶¶61-62, 68-72, 78, 80, 82-86, 93-104, 150-154, 223, 227, 231-232).

386. Defendants' reliance on the fact that Baby Powder has been "sold to families for over 100 years" and representation that J&J is "confident that our products do not contain asbestos and do not cause ovarian cancer," as alleged in ¶382, were false and misleading. As alleged in ¶¶128 and 224, J&J had acknowledged internally that talc did not have 100 years of safe use and they could not "say 'always'" when it comes to Baby Powder being asbestos-free. In addition, these statements concealed that: (i) asbestos had repeatedly been found in the Company's talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), and (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67, 230).

387. Defendants’ statement, as alleged in ¶382, that “scientific and regulatory bodies” such as the FDA had “fully reviewed the full body of scientific evidence on multiple occasions and found that it does not support the allegation that talc causes ovarian cancer” was false and misleading. In truth, (i) J&J had lied to the FDA as recently as 2016 regarding asbestos in its talc (¶¶150-154), and (ii) the scientific and regulatory bodies never had “the full body of scientific evidence” because J&J never disclosed that asbestos had been found in the Company’s talc and powders on numerous occasions. ¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228. The statement was also false and misleading because J&J knew that some scientific sources were actually “not as definitive or supportive and could be interpreted as suggesting a causal effect” between ovarian cancer and talc and that at least one had concluded that “perineal talc use may modestly increase the risk of invasive serous ovarian cancers.” ¶¶131 and 225. Finally, the statement was false and misleading in that it omitted that: (i) asbestos had repeatedly been found in the Company’s talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67, 230), and (iv) J&J had purposely influenced and manipulated regulators and scientists in order to protect the Company’s flagship product and reputation (¶¶61-62, 68-72, 78, 80, 82-86, 93-104, 150-154, 223, 227, 231-232).

388. On August 2, 2018, J&J filed its 2Q18 Form 10-Q with the SEC. Defendants disclosed that J&J and some of J&J's subsidiaries were involved in product liability litigation, but also represented that the Company had "substantial defenses":

Johnson & Johnson and certain of its subsidiaries are involved in numerous product liability claims and lawsuits involving multiple products. Claimants in these cases seek substantial compensatory and, where available, punitive damages. While *the Company believes it has substantial defenses*, it is not feasible to predict the ultimate outcome of litigation. The Company has established accruals for product liability claims and lawsuits in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. The Company accrues an estimate of the legal defense costs needed to defend each matter when those costs are probable and can be reasonably estimated. For certain of these matters, the Company has accrued additional amounts such as estimated costs associated with settlements, damages and other losses. To the extent adverse verdicts have been rendered against the Company, the Company does not record an accrual until a loss is determined to be probable and can be reasonably estimated. Product liability accruals can represent projected product liability for thousands of claims around the world, each in different litigation environments and with different fact patterns. Changes to the accruals may be required in the future as additional information becomes available.

* * *

Personal injury claims alleging that talc causes cancer have been made against Johnson & Johnson Consumer Inc. and Johnson & Johnson arising out of the use of body powders containing talc, primarily JOHNSONS® Baby Powder. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Lawsuits have been primarily filed in state courts in Missouri, New Jersey and California. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United

States District Court for the District of New Jersey. The Company has successfully defended a number of these cases but there have been verdicts against the Company, including a recent jury verdict of \$4.7 billion. The Company believes that it has strong grounds on appeal to overturn these verdicts. The Company has established an accrual for defense costs only in connection with product liability litigation associated with body powders containing talc.

389. Defendants' statements, as alleged in ¶388, were false and misleading. While defendants boasted of having "substantial defenses" to talc-related litigation, they omitted that: (i) asbestos had repeatedly been found in the Company's talc and powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67, 230), and (iv) J&J had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation (¶¶61-62, 68-72, 78, 80, 82-86, 93-104, 150-154, 223, 227, 231-232).

Z. October 2018 False and Misleading Statements

390. On October 31, 2018, J&J filed its third quarter 2018 Form 10-Q with the SEC. Defendants acknowledged that J&J and some of J&J's subsidiaries were involved in product liability litigation, but also represented that the Company had "substantial defenses":

Johnson & Johnson and certain of its subsidiaries are involved in numerous product liability claims and lawsuits involving multiple products. Claimants in these cases seek substantial compensatory and, where available, punitive damages. While *the Company believes it has*

substantial defenses, it is not feasible to predict the ultimate outcome of litigation. The Company has established accruals for product liability claims and lawsuits in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. The Company accrues an estimate of the legal defense costs needed to defend each matter when those costs are probable and can be reasonably estimated. For certain of these matters, the Company has accrued additional amounts such as estimated costs associated with settlements, damages and other losses. To the extent adverse verdicts have been rendered against the Company, the Company does not record an accrual until a loss is determined to be probable and can be reasonably estimated. Product liability accruals can represent projected product liability for thousands of claims around the world, each in different litigation environments and with different fact patterns. Changes to the accruals may be required in the future as additional information becomes available.

* * *

Personal injury claims alleging that talc causes cancer have been made against Johnson & Johnson Consumer Inc. and Johnson & Johnson arising out of the use of body powders containing talc, primarily JOHNSONS® Baby Powder. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Lawsuits have been primarily filed in state courts in Missouri, New Jersey and California. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the District of New Jersey. The Company has successfully defended a number of these cases but there have been verdicts against the Company, including a recent jury verdict of \$4.7 billion. The Company believes that it has strong grounds on appeal to overturn these verdicts. The Company has established an accrual for defense costs only in connection with product liability litigation associated with body powders containing talc.

391. Defendants' statements, as alleged in ¶390, were false and misleading.

While defendants boasted of having "substantial defenses" to talc-related litigation, they omitted that: (i) asbestos had repeatedly been found in the Company's talc and

powders (¶¶55-57, 59, 64, 73, 76, 81, 87-92, 223, 227-228), (ii) J&J had attempted to find ways to remove tremolite from its talc (¶¶58, 60, 228), (iii) J&J never adopted concentration methods that could detect the asbestos (¶¶63-67, 230), and (iv) J&J had purposely influenced and manipulated regulators and scientists in order to protect the Company's flagship product and reputation (¶¶61-62, 68-72, 78, 80, 82-86, 93-104, 150-154, 223, 227, 231-232).

VII. FRAUDULENT SCHEME AND COURSE OF BUSINESS

392. During the Class Period, defendants had actual knowledge of the misleading nature of the statements they made or acted in reckless disregard of the true information known to them at the time. In so doing, defendants participated in a scheme to defraud and committed acts, practices and participated in a course of business that operated as a fraud or deceit on purchasers of J&J securities during the Class Period.

VIII. ADDITIONAL SCIENTER ALLEGATIONS

393. As alleged herein, defendants knew or recklessly disregarded that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading and that such statements or documents would be issued or disseminated to the investing public: Defendants, by virtue of: (i) their receipt of information reflecting the true facts regarding J&J, (ii) their control over, and/or receipt and/or modification of J&J's allegedly materially misleading

misstatements and (iii) their senior leadership roles at the Company, which made them privy to confidential proprietary information concerning J&J, each participated in the fraudulent scheme alleged herein.

A. Defendant Gorsky

394. Gorsky knew or recklessly disregarded that his statements and the statements made by J&J in public filings with the SEC were false and misleading.³² As alleged herein, Gorsky admitted to paying very close attention to J&J's quality issues, including the allegations surrounding the Company's talcum powders specifically, and he also represented that he was intensely focused on whether J&J was acting in accordance with its corporate Credo. These admissions included the following:

- At the Company's April 2012 annual meeting, Gorsky spent over 30 minutes on Our Credo, promising that he was determined to keep it as the foundation at J&J and repeatedly assuring investors that J&J was adhering to the corporate credo's values. ¶¶116-117.
- On January 21, 2014, Gorsky admitted to having knowledge about whether the "Chief Medical and Chief Quality Officers [were] setting new benchmarks for medical safety" and whether J&J was "***monitoring the use of our end market products***" to "***ensu[re] that they are safe.***" ¶133.
- On January 12, 2015, Gorsky provided that "[q]uality and safety" was J&J's "***number-one priority***" and that he and his team at J&J had "over

³² These include the statements alleged in ¶¶253-254, 258-259, 263-264, 269, 271-275, 277, 281-282, 284, 286, 296-297, 307, 315-316, 324-327, 329, 333, 335, 344, 353-356, 358, 360-361, 365, 367-368, 382, 388, and 390.

the last few years” “made a number of changes . . . to *make sure that we addressed any of the outstanding issues that we were facing.*” ¶137. By the time Gorsky made this admission, J&J had suffered the first verdict linking talc to ovarian cancer and was facing mounting claims brought by federal class action plaintiffs, state court litigants, and the Attorney General of Mississippi. ¶¶126, 136. The safety of J&J’s talcum powders was thus a well-known “outstanding issue[.]”

- On April 23, 2015, Gorsky admitted the importance of Johnson’s Baby Powder and the Company’s other consumer brands, noting that “our consumer, our iconic consumer brands have been, and continue to be, perhaps *the greatest connection that we have with people, with consumers all over the world.*” ¶140.
- On September 6, 2017, Gorsky admitted to paying attention to “the significant amount of clinical information [and] control data” involving talc and talcum powders, including from agencies like the National Cancer Institute (“NCI”) and FDA, and claimed to have *sufficient knowledge* to form an opinion on “the safety of talc.” ¶176. Gorsky also made clear that *he had assessed sufficient data surrounding J&J’s talcum powders* in order to form an opinion about J&J’s defense in the talcum powder litigation. ¶176.
- Also on September 6, 2017, Gorsky *admitted to closely following the ovarian cancer litigation developments*, referencing St. Louis as one of “the early results,” as well as “earlier findings in New Jersey” and “the first outcome in California.” ¶176.
- On May 16, 2018, Gorsky admitted to having *knowledge about the ingredients in J&J’s Baby products and whether J&J had “taken out many of the concerning . . . ingredients*, that . . . mothers didn’t want in their products.” ¶206.
- Also on May 16, 2018, Gorsky admitted to reviewing the Company’s “clinical data and information” regarding talc’s safety. ¶206.
- Also on May 16, 2018, Gorsky promised that he and J&J had an “absolute commitment [to] hold ourselves accountable and . . . fulfill all of our Credo responsibilities where we always keep the customer and patients at the center of everything we do.” ¶207.

- On July 17, 2018, Gorsky admitted to knowing whether J&J is “always guided by our credo” and remains committed to it, and whether the Credo is still relevant. ¶221.
- Also on July 17, 2018, Gorsky *admitted to having knowledge about J&J’s baby products, including whether they are “science-based and professionally endorsed.”* ¶221.
- Also on July 17, 2018, Gorsky *admitted to paying attention to the talc litigation*, including whether J&J’s products contained asbestos or caused ovarian cancer. ¶222. In addition, Gorsky claimed to know whether scientific and regulatory bodies had “fully reviewed the full body of scientific evidence.” ¶222.

395. Gorsky’s scienter is further bolstered by his actions which illustrate that he paid special attention to product quality issues, including the ongoing litigation surrounding J&J’s talcum powders. Indeed, as alleged in ¶¶116-118, from his first day on the job as CEO, Gorsky knew investors were deeply concerned over quality issues and J&J’s reputation.

396. In addition, the June 6, 2017 email to Gorsky and the Board of Directors that included a “*deck under the heading of ‘Update on Talc Litigation’ in Tab 7 that discusses reputational risk*” illustrates that Gorsky was made aware of, and his attention was on, the issues surrounding talc. ¶171.

397. Defendant Gorsky’s scienter is further evidenced by the fact that, as a long time executive in the consumer and pharma industries, he had a *heightened understanding of the troubles that revelation of unethical and/or illegal business conduct could bring* to the Company and himself. As alleged in ¶¶21, 113-114, he

had been “actively involved” at Janssen when “Janssen managers effectively embraced off-label promotion” and Janssen exhibited “especially unscrupulous” behavior, that “recklessly put at risk the health of some of the most vulnerable members of society” and showed “blatant disregard for systems and laws.” This conduct led to Janssen’s \$2.2 billion settlement with the Department of Justice. ¶¶113-114.

398. Similarly, as alleged in ¶115, Gorsky was warned by the FDA while he was at Novartis that representations made by the company “suggested that [the product in question was] safer . . . than ha[d] been demonstrated.” This experience alerted Gorsky to the importance of not making false and misleading statements regarding product safety. And as alleged in ¶115, Gorsky was deposed regarding J&J’s DePuy unit, which would later be hit with a jury verdict of over \$1 billion, and had “personal involvement” in preparing corporate communications regarding the defective hip implants at issue in the case.

B. Defendant Caruso

399. Caruso knew that the statements made by J&J in public filings with the SEC were false and misleading.³³ As the Chief Financial Officer of the Company and a signatory to those filings, Caruso was responsible for ensuring that the statements

³³ These include the statements alleged in ¶¶253-254, 258-259, 263-264, 271- 275, 281-282, 286, 296-297, 307, 315-316, 324-327, 329, 333, 344, 353-356, 365, 388, and 390.

contained therein were not false or materially misleading. In addition, as CFO, Caruso would ultimately be responsible for the Company's assessment of the potential financial outcomes resulting from the talc litigation, requiring Caruso to be familiar with the facts and evidence in those cases. In addition, Caruso led J&J's investor relations activities during the Class Period. As such, he certainly would have known that investors were intensely focused on quality issues throughout the Class Period. This, coupled with J&J's spreading talcum powder litigation, effectively guaranteed that Caruso had access to the information that defendants withheld from investors during the Class Period.

C. Defendant Goodrich

400. Goodrich knew that her statements, and corporate statements that she created and contributed to, as alleged in ¶¶267, 288, 294, 301, 340, 359, 380, were false and misleading. As alleged in ¶126, Goodrich personally worked on the language to be included on the "Our Safety & Care Commitment" website, which was available as of January 7, 2014. And while the "Our Safety & Care Commitment" website touted talc's "safety profile," "long history of safe use," and use "for over 100 years," Goodrich knew that the use of talc had not actually been safe for 100+ years, and may not have even occurred with regards to "cosmetic talc." ¶128. In addition, although the website implied that J&J's talc products have always been asbestos-free, Goodrich knew that J&J could not accurately "say 'always.'" ¶128. She also knew or

was reckless in making additional false misleading statements, including: (i) on May 2, 2016, that J&J “has provided consumers with a safe choice for cosmetic powder products” “[f]or over 100 years,” (ii) on November 16, 2017, that “Johnson’s Baby Powder has been around since 1894 and it does not contain asbestos or cause mesothelioma or ovarian cancer,” and (iii) in April 2018, that “Johnson’s Baby Powder has been used for more than 120 years and it does not contain asbestos.” ¶¶302, 340, 359.

401. Goodrich also knew that it was false and misleading to represent (i) on the “Our Safety & Care Commitment” website, that talc’s purported safety was supported by “more than 30 years of research,” examination by “[v]arious agencies and governmental bodies” supported talc’s safety, and “[m]any research papers and epidemiology studies” “published since the early 1990s” “have found talc to be safe,” (ii) on February 23, 2016, that talc’s safety is “supported by decades of scientific evidence,” and that J&J believed this to be true, and (iii) on May 2, 2016, that “30 years of studies by medical experts around the world . . . continue to support” cosmetic talc’s safety, and that “[m]ultiple scientific and regulatory reviews have determined that talc is safe for use . . . and the labeling on Johnson’s Baby Powder is appropriate.” ¶¶266, 294, 302. As alleged in ¶131, Goodrich in fact knew that other scientific sources not cited on “Our Safety & Care Commitment” website could actually “be interpreted as suggesting a causal effect” between talc and ovarian cancer,

including from IARC and the American Cancer Society. She also knew that “[e]ven some of the studies” cited by J&J on its website sent “mixed messages,” including a study recognizing that ““perineal talc use may modestly increase”” the risk of ovarian cancer. ¶131.

D. Defendant Casalvieri

402. Casalvieri knew that her statements, as alleged in ¶292, claiming that scientific studies, “assessments by external experts,” and J&J’s “company testing” supported talc’s safety, were false and misleading. She *admitted to examining “assessments by external experts”* and having *knowledge of J&J’s “company testing,”* and emphasized that “[a]s a toxicologist in our Consumer business,” “*my job is to make certain a product is safe.*” ¶292. Thus, Casalvieri would have been informed of the very facts making her statement misleading. By holding herself out as an expert on the safety of J&J’s talc products and “assur[ing] women and caregivers who use our talc products” of their safety, ¶292, Casalvieri publicly represented that she fully understood the possible dangers of talc when making her false and misleading statements. Casalvieri’s scienter is further bolstered by the fact that she was featured on the updated “Our Safety & Care Commitment” website available as of December 25, 2015, which represented that “[w]e *have carefully assessed all available data on talc,*” including the “body of research and clinical evidence.” ¶288.

403. In addition to these admissions and representations, Casalvieri's scienter is also evidenced by her direction of J&J's fraudulent conduct in 2005. Indeed, Casalvieri *directed J&J's project "to defend talc,"* which included "*develop[ing] documents* that scientifically support the lack of a relationship of talc and ovarian cancer," including secretly funding a meta-study supportive of talc. ¶¶94-95, 97-99. Casalvieri also knew, but failed to disclose, that J&J had worked *under her direction* "to assure a good outcome" for talc against the NTP. ¶95. Her centrality to that effort is clear: she was *personally congratulated* for her work when the NTP withdrew talc from consideration as a possible carcinogen. ¶104. Casalvieri knew, but failed to disclose, that the decision by the NTP "was *a direct result of [J&J's] efforts* in coordination with Luzenac and CTFA," ¶104, efforts which she herself directed. As the director of the project to defend talc, Casalvieri also received detailed updates from Steve Mann regarding the day-to-day of these efforts, including J&J's attempt at getting its own experts embedded in the IARC process. ¶¶100-102. Finally, Casalvieri worked closely with Mann to "defend talc" within less than a year after Mann was informed that Forensic Analytical and a news station had discovered asbestos in Johnson's Baby Powder. ¶¶88, 94-96, 100-102. It is implausible that Casalvieri would not also have known of this finding.

E. Defendant Peterson

404. Peterson knew or was reckless in not knowing that her statements alleged in ¶¶261 and 374, were false and misleading. As alleged in ¶¶118 and 212, Peterson was specifically brought on to J&J’s leadership team as a “corporate fixer” just prior to the start of the Class Period, with an emphasis on “fixing the consumer and supply chain issues once and for all.” ¶118. As Group Worldwide Chair from 2012 through 2018, Peterson led the JJCI business that produced Johnson’s Baby Powder and was responsible for the supply chain and quality of that product, along with other aspects of the business. ¶¶23, 118. During J&J’s July 16, 2013 earnings call, Peterson acknowledged: *“I have accountability for some of the Company’s key enterprise functions – supply chain, including quality”*

405. During the Class Period, Peterson also represented to investors that she knew whether or not “all of [J&J’s] businesses” were “trying to ensure . . . the highest standard of quality for the safety and care of . . . patients and consumers,” and held herself out as knowing whether J&J had “identified corrective actions” and had “immediately taken those corrective actions.” ¶125. Indeed, she specifically stated that she was paying attention to and implementing J&J’s “processes and systems so that [J&J had] early warning systems” to monitor potential product problems. ¶261. Peterson’s role also involved overseeing details of J&J’s “global supply chain,”

including “ensuring that all of [J&J’s material] suppliers . . . are thoroughly reviewed, thoroughly managed, and that they are living up to [J&J’s] quality standards.” ¶261.

406. Finally, Peterson’s sudden *retirement in 2018 was highly suspicious* and contributes to an inference of her scienter. As alleged in ¶¶211-212, (i) Peterson’s retirement was close in time to the first jury finding in favor of a plaintiff alleging harm from asbestos in J&J’s talcum powders, (ii) Peterson had been brought in to fix the JJCI business’s quality control issues but elected to retire at a time when the business had very serious quality control issues still unresolved, (iii) Peterson had taken on an additional leadership role only one year prior, (iv) J&J was required to shuffle various executives around as a result of Peterson’s departure to leave, indicating lack of a premeditated transition plan, and (v) at least one analyst following J&J expressed surprise at the announcement due to the strange timing.

F. Defendant Glasgow

407. Glasgow knew that her statements, as alleged in ¶¶278, 311, 321, were false and misleading. As alleged in ¶321, on January 24, 2017, Glasgow emphasized that she and others at J&J meticulously assembled and reviewed all of the available data on the safety of talc, which included “decades of scientific work”:

When it comes to the safety of the products we make, we’re just like you. . .

We want all the information we can get. We seek out the guidance of experts and we monitor the latest science to see if it impacts any of our

products. *We also listen to the people who use our products* so we can take their experiences into account. . . .

[T]here is no information more important than our research on scientific data and safety. We go beyond the findings of a single study because we must ensure we've assembled all of the available data from multiple scientific areas to reach conclusions based on evidence. One opinion or study can't outweigh *decades of conclusive, scientific, evidence-based findings*. As a scientist and, equally important, as a parent myself, I can tell you the science is clear: Cosmetic talc is, and has been, safe for use in consumer products.

We are all mothers, fathers, and consumers ourselves; we understand and take seriously our responsibility to give you the information you need to make your own decisions. . . . We choose to include these ingredients not simply because we've used them for decades. We include them because *decades of scientific work support their safety*.

408. In addition, as alleged in ¶278, Glasgow represented that she and the rest of J&J “feel, as scientists, an obligation to continue to take our research to the next level by *looking at all the science*.” Glasgow held herself out as having reviewed “30 years of scientific studies and regulatory reviews,” along with “the medical facts and science” regarding the Company’s talcum powder products. ¶311. Similarly, she represented that she had reviewed the studies, “science, research and clinic evidence” regarding the safety of talc. ¶311. In sum, Glasgow knew or recklessly disregarded the wealth of scientific information within J&J regarding the dangers of its talcum powders.

G. Defendant Sneed

409. Sneed knew that his statements, as alleged in ¶256, were false and misleading. As VP of Global Corporate Affairs, Sneed was involved with J&J’s

public relations and knew that checking the accuracy of corporate statements was vitally important. Indeed, he admitted that “[t]he reputation of J&J is very important to us” and that “[w]e take it very seriously” when he spoke to investors on April 25, 2013. ¶123. He also represented that he knew about (i) J&J’s efforts to “get past some of the challenges we’ve had as a business,” (ii) what J&J does when it makes “mistakes,” (iii) “the values that are behind J&J,” (iv) whether J&J “really embraced transparency,” and (v) whether J&J had a history of “car[ing] unconditionally for others.” ¶256. Thus, he knew or recklessly disregarded that his statements were false and misleading and omitted material information.

H. Additional Allegations Supporting Defendants’ Scienter

410. In addition to the facts alleged in ¶¶394-409, defendants’ scienter is further established by the detailed allegations regarding the importance of Johnson’s Baby Powder to J&J’s overall business and reputation, J&J’s purposely inadequate test methods, J&J’s massive fraudulent scheme and pervasive corporate misconduct, and numerous red flags that the Company had received.

1. Johnson’s Baby Powder Was Absolutely Critical to Consumers’ Trust and J&J’s Overall Business and Reputation

411. As alleged herein, J&J has repeatedly recognized the vital importance of Johnson’s Baby Powder for the Company’s business. Because J&J is in the business of selling consumer goods, drugs, and medical devices, its success depends on

consumer trust. And because Baby Powder is “*a primary link to the positive J&J name in the public mind,*” a recognition that the talc used in it was carcinogenic “*would have a major ripple effect*” for J&J. ¶93. Indeed, in 2018, J&J’s counsel admitted that Johnson’s Baby Powder “is about the trust of Johnson & Johnson,” because “[J&J] know[s] that the people who use this product are mothers and babies . . . and these are Johnson & Johnson’s customers,” so “this *is* about trust.” ¶120. In further recognition of the dire stakes, in 2017, J&J’s Board of Directors spent an entire slide deck on an “Update on Talc Litigation” that discussed “*reputational risk.*” ¶171. And in *sworn testimony*, J&J’s longstanding corporate representative recognized the truth that “*it would be very, very bad for business* if it ever came out that the baby powder or any of Johnson & Johnson’s talc products ever contained asbestos.” ¶43 n.3.

412. J&J has also provided additional detail regarding the heightened corporate concern over Johnson’s Baby Powder. According to *J&J’s own admissions*, “despite the depth and breadth of its product lines,” the Company remains known as “the Baby Company.” ¶46. And Johnson’s Baby Powder has been ““the cornerstone of [the] baby products franchise.”” ¶46. Indeed, J&J admitted that Johnson’s Baby Powder is a ““flagship product,” ““sacred cow,” “institution,” “the most widely recognized fragrance in the United States,” and “one of the most familiar and trusted products in the world.” ¶¶43-44, 47, 87. J&J’s longtime corporate

representative has even admitted *under oath* that Johnson’s Baby Powder is among “the top one or two products that people think of when they think of J&J.” ¶43 n.3.

413. Other admissions by J&J illustrate the depth and reach of the public’s relationship with Johnson’s Baby Powder, and thus the potentially devastating impact to the Company’s reputation, were the truth to surface. For example, J&J admits that “[i]f you’ve ever cared for a baby, you’ve probably had JOHNSON’S Baby Powder in your home.” ¶48. Thus, if it were to come out that the Baby Powder contained asbestos, millions of parents would face the horrifying realization that they had unknowingly exposed their children to asbestos through a Johnson & Johnson product. The betrayal of trust for millions of consumers would be all the more disturbing because of J&J’s longstanding efforts to convince the public to think of J&J “as a lifetime friend of the family” and to create an association between Baby Powder and “the parent-infant bond.” ¶48.

414. And, following the *Reuters* report’s revelations, financial analysts specifically recognized the significant negative impact to J&J’s overall business and reputation. For example, on December 14, 2018, CFRA lowered its opinion on J&J from “buy” to “hold” and dropped their price target by \$30 per share. ¶235. The CFRA report made clear that the new information and analysis revealed by *Reuters* would cause “significant damage” to J&J’s “valuable brand name” because consumer trust is “critical” to J&J’s overall “success.” As CFRA explained: “We see today’s

news potentially impacting sales of everything from baby shampoo to prosthetic hips. Given these elevated risks, we no longer feel JNJ shares are attractive at recent prices.” And, in a January 25, 2019 report, CFRA again emphasized the importance of the reputational damage: “Brand-name *reputation is critically important for the success of [J&J’s] Consumer segment*, in our view.” ¶241. And, recognizing the significant negative impact to J&J’s overall business and reputation, CFRA noted: “Due to the importance of brand power and consumer trust, we think *allegations from a Reuters story published in December 2018 could have a meaningful negative impact on JNJ’s Consumer segment, as well as the Medical Devices segment to a lesser extent.*”

2. J&J Purposely Avoided Testing Methods Capable of Finding the Asbestos in the Company’s Talc and Powders

415. As alleged herein, J&J was notified that a concentration technique was necessary to find any asbestos present in the talc, and it was further informed that the use of a concentration method had shown that there was in fact asbestos in J&J’s talc. ¶¶63-64, 230. Yet, J&J has never adopted a concentration method for testing its talc and powders for asbestos, instead finding such methods to be “disturbing” and “too sensitive.” ¶¶65-67, 230. J&J’s determined avoidance of methods proven capable of detecting trace amounts of asbestos exposes the Company’s knowledge that the talc was, and likely still is, contaminated with asbestos.

3. J&J Conducted a Widespread, Longstanding Fraudulent Scheme

416. The sheer pervasiveness and length of the alleged corporate misconduct and fraudulent scheme to cover up the asbestos contamination and dangers of its talcum powders also demonstrates defendants' scienter. Examples of such malfeasance include the following:

June 1971	J&J tells the public that there is no asbestos in its powder, despite recognizing "unavoidable trace amounts" of tremolite in its talc and admitting internally only a month later that the talc had "trace amounts of fibrous minerals (tremolite/actinolite)" and that three independent labs had found "fibrous minerals" in the talc. ¶¶52, 54-55.
November 1972	J&J memorandum brands public health officials and doctors "Antagonistic Personalities," including one researcher who had found asbestos in Baby Powder. ¶61.
February 1973	J&J secretly works on a method to remove tremolite from its talc and considers seeking profitable patents, but ultimately decides to keep it secret rather than "let the whole world know." ¶58.
May 1973	J&J report warns that a concentration method "may be too sensitive" since it finds tremolite asbestos in the Vermont talc. ¶64.
August 1973	J&J asks the Dutch Consumer Organization to not make public their finding of "asbestos in JOHNSON's Baby Powder." ¶59.
December 1973	J&J contributes to a CTFA letter seeking to influence the FDA after recognizing that if the regulator changed the method, "we may have problems." ¶62.
April 1974	J&J authorized secret asbestos-destruction experiments in Colorado and once again considered seeking a profitable patent rather than informing the public of the asbestos. ¶63.
February 1975	J&J admits internally that it "want[s] to exclude concentration techniques," that it is "looking at this method very quietly," and that it wants "to avoid promotion of this approach." ¶65.

March 1975	J&J memorandum illustrates that J&J sponsored “talc safety studies” to “neutralize or hold in check data . . . generated by investigators,” and that going forward J&J should carry out more studies, which would provide “maximal leverage for defending the product.” ¶68.
1976	J&J assures the FDA that no asbestos had been detected in its talc produced between December 1972 and October 1973, failing to disclose that at least three tests from 1972-1975 had found asbestos in the talc. ¶227.
November 1976	J&J’s Ashton finds a proposal that would lead to concentration methods “disturbing” because such methods would make the talc industry “hard pressed in supporting purity claims.” ¶66.
August 1977	J&J Status Report illustrates that the Company had been conducting a “talc safety defense program,” which consisted of “various J&J sponsored studies” disseminated to scientists and medical professionals. J&J acknowledged that these studies had been successful in deterring “disruptive influences.” ¶71.
December 1977-January 1978	J&J “Special Talc Study” report illustrates J&J’s continued efforts to “monitor and defend against consumerist, scientific and regulatory attitudes/trends which could impact adversely on the safety image and marketability of cosmetic talcs,” as well as to “generate or provide necessary data to support and reinforce the safety of our baby powder.” ¶72.
1989	Amidst talc and ovarian cancer research, J&J sells the primary source of J&J talc since 1966 and destroys most of the mine records. ¶75.
1993	With government interest in talc growing, J&J had implemented “a strategy to keep J&J at the forefront of cosmetic talc, and to insure that [it] ha[d] worldwide oversight on talc issues.” ¶78.
September 1997	J&J participates in “inept,” “inaccurate,” and “outright false” representations regarding talc and ovarian cancer, according to J&J’s own consultant. ¶80.
2000	J&J and its talc supplier work with lobbying group CRE to defend against the NTP, using the illusory “fatal flaw” strategy and “the introduction of doubt” to avoid talc being considered as a carcinogen. ¶¶82-85. CRE’s submission to the NTP falsely claims that it has no affiliation with any industry or company. ¶83.

February 2002	J&J's Mann and Telofski recognize the inconsistency between the "fatal flaw" strategy (asserting that talc before 1976 had asbestos) and J&J's claim that the source of its talc "never" contained asbestos. ¶87.
February 2004	Rather than inform the public that Forensic Analytical had found asbestos in Johnson's Baby Powder, J&J calls its talc supplier "frantically" about the asbestos and sought advice from RJ Lee. ¶¶88-91.
October 2004	Months after learning of asbestos in Johnson's Baby Powder, Mann tells numerous J&J employees that it looks like J&J "need[s] to call upon major corporate resources and utilize all our power to defend against" the NTP, as an unfavorable ruling "would have a major ripple effect as J&J Baby Powder is a primary link to the positive J&J name in the public mind." ¶93.
February 2005	<p>Defendant Caselvieri and Mann lead the project "to defend talc." ¶94. Numerous J&J employees are made aware that the project was "to assure a good outcome" with the NTP, "develop documents that scientifically support the lack of a relationship of talc and ovarian cancer," and "monitor[] closely NTP activity." ¶95.</p> <p>Gerard Gries of J&J states that the "critical question" that would determine J&J's strategy is "what the chances are that we can prevent [the] classification" of talc as a carcinogen. ¶96.</p> <p>J&J works with its talc supplier to secretly fund a meta-study for submission to the NTP. ¶¶97-99.</p>
June 2005	J&J email from Mann to 15 J&J employees details J&J's efforts to influence the IARC decision on talc by getting its own experts embedded in the process. ¶100.
July 2005	J&J's Nettesheim (VP of R&D at Johnson's Worldwide) shares information with others at J&J about the Company's efforts to influence IARC. ¶101.

August 2005	<p>J&J's Matheson (Chief Technology Officer of the Consumer division from 1994-2007 and 2012-2014) asks Mann for an update regarding J&J's efforts to influence IARC. ¶101.</p> <p>Mann reports to Matheson, Caselvieri, and others regarding J&J's efforts to get its experts embedded in the IARC process, including Hopkins. ¶¶101-102.</p> <p>Matheson asks Mann if there are other "specific actions we should consider," and Mann reports that he is looking for what else they could do to impact IARC's process. ¶102.</p>
October 2005	<p>Less than two years after learning of asbestos in Johnson's Baby Powder, Mann sends a victory email to over 30 J&J employees, including Caselvieri, stating that the NTP's withdrawal of talc from consideration as a carcinogen is "a direct result of our efforts in coordination with Luzenac and CTFA. We did it!" ¶104.</p> <p>Caselvieri and Mann are specifically congratulated for their "[g]reat job" and "major accomplishment for J&J." ¶104.</p>
May 2008	J&J's Ellen Kurtz shuts down True's questioning of the safety of talc. ¶109.
March 2016	J&J tells the FDA that no "asbestos-form structures have ever been found during any testing" of J&J's talc. ¶151.

4. J&J Knew of Asbestos Being Found in Its Talc and Powders and Received Numerous Red Flags

417. The many asbestos findings that the Company was aware of, along with the many red flags received by J&J, also collectively serve as strong evidence of defendants' scienter. That J&J and the Individual Defendants were unquestionably aware of the adverse analyses of its talc and powders is all the more certain as J&J was sued by numerous plaintiffs alleging that the Company's talcum powders had caused their ovarian cancer and mesothelioma during the Class Period. In addition, as defendant Glasgow admitted, J&J had "assembled all of the available data" on talc,

sought out “the guidance of experts,” “monitor[ed] the latest science,” and “listen[ed] to the people who use [its] products.” ¶¶321, 407. Finally, as alleged in ¶¶38 and 40, Dr. Susan Nicholson, VP of Safety Surveillance and Risk Management, spent months reviewing the safety of talc, and Nicholson met with the CMO of J&J, Dr. Joanne Waldstreicher, in November 2015 to discuss the safety of talc and potential asbestos contamination. In the midst of all of this internal and external attention on its talc, J&J and the individual defendants either knew about or recklessly disregarded the numerous findings and warnings of asbestos in its products. Examples of the red flags defendants knew of include the following:

1969	General Johnson and pediatricians “express[ed] concern” about potential “adverse effects on the lungs of babies and mothers,” and J&J knew that “a furor” could be created “if it became known” that J&J’s talc “contained any significant amount of Tremolite.” ¶52. J&J further recognized that it “could become involved in litigation.” ¶53.
July 1971	J&J memorandum recognized that J&J’s talc had “trace amounts of fibrous minerals (tremolite/actinolite)” and that three independent laboratories had found “trace amounts of fibrous minerals” in the talc. ¶55.
November 1971	Mount Sinai researcher Arthur Langer informed J&J that he found asbestos in J&J’s “baby talc.” ¶61.
1972	Professor Hutchinson found “incontrovertible asbestos” in a Shower to Shower sample he had received from J&J. ¶56.
August 1972	FDA informed J&J that asbestos fibers were found in J&J’s talcum powder product, Shower to Shower. ¶57. J&J memorandum admitted internally that tremolite fibers “could be present in trace amounts.” ¶57.
May 1973	J&J report recognized that J&J consultant Dr. Pooley found tremolite asbestos in Vermont talc when using concentration

	method. ¶64.
August 1973	Dutch Consumer Organization notified J&J of “asbestos in JOHNSON’s Baby Powder.” J&J asked that it not be made public. ¶59.
December 1977-January 1978	J&J report illustrated that asbestos was found in Johnson’s Baby Powder and J&J’s talc. ¶¶72-73.
November 1994	Then-CEO Ralph Larson received a letter alerting him to the scientific evidence of an association between talc and ovarian cancer. ¶79.
September 1997	J&J’s Chudkowski is warned that denying studies showing an association between ovarian cancer and talc risked being “perceive[d] [like] the cigarette industry: denying the obvious in the face of all evidence to the contrary.” ¶80.
April 1998	J&J’s legal counsel received a letter from Dr. Alice Blount stating that she believed “Johnson & Johnson’s Vermont talc contains trace amounts of asbestos,” and identifying Johnson’s Baby Powder as the sample from her 1991 paper containing asbestos “[n]eedles and fibers.” ¶81.
2004	KCRA TV3 and Forensic Analytical discovered that Johnson’s Baby Powder contains asbestos and J&J’s Marc Monseau, Sarah Colamarino, Steve Mann, John Hopkins, and Bill Ashton are notified. ¶¶88-89, 91.
April 2008	J&J’s True recognized that “talc is not actually safe for use around babies.” ¶106.
2009	MSDS sheet from J&J’s talc supplier warned of ovarian cancer risk and that talc was only “not classifiable as a human carcinogen” if it did not contain asbestos. ¶105.
April 2012	J&J Audit of RJ Lee illustrated that the outside laboratory did not think J&J’s testing method was “an optimal method for asbestos testing,” and the report also details numerous problems with the asbestos testing facility. ¶110.
October 2013	<p>Draft text for J&J’s website recognized that “we cannot say ‘always’” asbestos-free, talc had not been used safely for over 100 years, and cosmetic talc had not been used for 100 years. ¶128.</p> <p>The draft also indicated that some studies could be read as suggesting a causal effect between talc and ovarian cancer, some</p>

	of J&J's cited studies sent "mixed messages," and one of J&J's cited studies even acknowledged the potential increase in risk from talc use. ¶131.
2017	J&J's legal counsel visited Langer and is informed that he stood by his finding of asbestos in J&J's talc. ¶61 n.8.
June 2017	J&J's Board of Directors explored the "reputational risk" from the talc litigation. ¶171.

IX. LOSS CAUSATION/ECONOMIC LOSS

418. During the Class Period, defendants made numerous false and misleading statements and omissions of material facts necessary to render those statements not false or misleading, which artificially inflated or maintained inflation in J&J's stock price.

419. As detailed herein, defendants' false and misleading statements and omissions maintained artificial inflation in the price of J&J securities by misrepresenting and concealing the relevant truth about J&J's talc and talcum powder products, including the asbestos contamination, and the associated reputation and litigation risks. Lead Plaintiff and investors purchased J&J stock at these inflated prices and suffered damage when the price of J&J stock declined upon the revelations of the relevant truth.

420. The inflation in J&J's stock was dissipated through a series of partial disclosures of the relevant truth about J&J's talc and attendant reputation and litigation risks. The resulting significant stock price declines upon release of truthful

information and related increased risks were due to firm-specific fraud-related disclosures, and not a result of market or industry. The following examples are not exhaustive because fact and expert discovery have yet to commence.

421. As a result of disclosures on September 27, 2017, January 30, 2018, February 5 and 7, 2018, July 12, 2018, and December 14, 2018, J&J's stock price suffered statistically significant declines. *See* §V.J. Individually and collectively, these drops removed the inflation from J&J's stock price, causing real economic losses to investors who had purchased the stock during the Class Period.

422. In sum, as detailed above, the rapid declines described herein served to remove artificial inflation from the price of J&J securities, and were direct and foreseeable consequences of the revelation of the relevant truth concealed by defendants.

X. NO SAFE HARBOR

423. J&J's verbal "Safe Harbor" warnings accompanying its oral forward-looking statements ("FLS") issued during the Class Period, if any, were ineffective to shield those statements from liability.

424. Defendants are also liable for any false or misleading FLS pleaded because, at the time each FLS was made, the speaker knew the FLS was false or misleading and the FLS was authorized and/or approved by an executive officer of J&J who knew that the FLS was false.

425. None of the alleged misstatements made by defendants were assumptions underlying or relating to any plan, projection or statement of future economic performance, nor were any of the projections or forecasts made by defendants expressly related to or stated to be dependent on those historic or present tense statements. On the contrary, the alleged misstatements concealed critical information about J&J's products, conduct, and litigation and reputational exposure.

**XI. APPLICABILITY OF PRESUMPTION OF RELIANCE:
FRAUD ON THE MARKET**

426. Plaintiff will rely upon the presumption of reliance established by the fraud-on-the-market doctrine in that, among other things:

- (a) Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- (b) The omissions and misrepresentations were material;
- (c) The Company's stock traded in an efficient market;
- (d) The misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of the Company's stock; and
- (e) Plaintiff and other members of the Class purchased J&J stock between the time defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

427. At all relevant times, the market for J&J stock was efficient for the following reasons, among others:

(a) J&J's stock has long been listed and actively traded on the NYSE, a highly efficient and automated market;

(b) As a regulated issuer, J&J filed periodic public reports with the SEC; and

(c) J&J regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the major news wire services and through other wide-ranging public disclosures, such as communications with the financial press, securities analysts and other similar reporting services.

XII. CLASS ACTION ALLEGATIONS

428. Lead Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons who purchased J&J publicly traded securities during the Class Period (the "Class"). Excluded from the Class are defendants, directors and officers of J&J and their families and affiliates.

429. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. During the Class Period, J&J had more than 2.5 billion shares of stock outstanding, owned by thousands of persons.

430. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class predominate over questions which may affect individual Class members, and include:

- (a) Whether the 1934 Act was violated by defendants;
- (b) Whether defendants omitted and/or misrepresented material facts;
- (c) Whether defendants' statements omitted material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;
- (d) Whether defendants knew or recklessly disregarded that their statements were false and misleading;
- (e) Whether the price of J&J's stock was artificially inflated; and
- (f) The extent of damage sustained by Class members and the appropriate measure of damages.

431. Plaintiff's claims are typical of those of the Class because plaintiff and the Class sustained damages from defendants' wrongful conduct.

432. Plaintiff will adequately protect the interests of the Class and has retained counsel who are experienced in class action securities litigation. Plaintiff has no interests which conflict with those of the Class.

433. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

XIII. CLAIMS FOR RELIEF

COUNT I

For Violations of Section 10(b) of the 1934 Act and Rule 10b-5 Promulgated Thereunder Against All Defendants

434. Plaintiff repeats and realleges each and every allegation set forth above in ¶¶1-433 as if fully set forth herein. This Count is asserted pursuant to §10(b) of the 1934 Act and Rule 10b-5 promulgated thereunder by the SEC against all defendants.

435. As alleged herein, throughout the Class Period, defendants, individually and in concert, directly and indirectly, by the use of the means or instrumentalities of interstate commerce, the mails and/or the facilities of national securities exchanges, made untrue statements of material fact and/or omitted to state material facts necessary to make their statements not misleading and carried out a plan, scheme and course of conduct, in violation of §10(b) of the 1934 Act and Rule 10b-5 promulgated thereunder. Defendants intended to and did, as alleged herein: (i) deceive the investing public, including plaintiff and members of the Class; (ii) artificially inflate and maintain the prices of J&J common stock; and (iii) cause plaintiff and members of the Class to purchase J&J common stock at artificially inflated prices.

436. The Individual Defendants were individually and collectively responsible for making the false and misleading statements and omissions alleged herein and having engaged in a plan, scheme and course of conduct designed to deceive plaintiff and members of the Class, by virtue of having made public statements and prepared, approved, signed and/or disseminated documents that contained untrue statements of material fact and/or omitted facts necessary to make the statements therein not misleading.

437. As set forth above, defendants made their false and misleading statements and omissions and engaged in the fraudulent activity described herein knowingly and intentionally, or in such a deliberately reckless manner as to constitute willful deceit and fraud upon plaintiff and the other members of the Class who purchased J&J common stock during the Class Period.

438. In ignorance of the false and misleading nature of defendants' statements and omissions, and relying directly or indirectly on those statements or upon the integrity of the market price for J&J common stock, plaintiff and other members of the Class purchased J&J common stock at artificially inflated prices during the Class Period. But for the fraud, plaintiff and members of the Class would not have purchased J&J common stock at such artificially inflated prices. As set forth herein, when the true facts were subsequently disclosed, the price of J&J common stock declined and plaintiff and members of the Class were harmed and damaged as a direct

and proximate result of their purchases of J&J common stock at artificially inflated prices and the subsequent decline in the price of those securities when the truth was disclosed.

439. By virtue of the foregoing, defendants are liable to plaintiff and members of the Class for violations of §10(b) of the 1934 Act and Rule 10b-5 promulgated thereunder.

COUNT II

For Violation of Section 20(a) of the 1934 Act and Rule 10b-5 Against Defendants J&J, Gorsky, Caruso, Peterson, and Sneed

440. Plaintiff repeats and realleges each and every allegation set forth above in ¶¶1-439 as if fully set forth herein. This Count is asserted pursuant to §20(a) of the 1934 Act against defendants Gorsky and Caruso. As alleged above, J&J violated §10(b) of the 1934 Act and Rule 10b-5 promulgated thereunder by making false and misleading statements in connection with the purchase and sale of J&J common stock and by participating in a fraudulent scheme and course of business or conduct throughout the Class Period. This fraudulent conduct was undertaken with scienter and the Company is charged with the knowledge and scienter of each of the Individual Defendants who knew of or acted with deliberate and/or reckless disregard of the falsity of the Company's statements and the fraudulent nature of its scheme during the Class Period.

441. As set forth above, defendants Gorsky, Caruso, and Sneed were controlling persons of J&J during the Class Period, and defendant Peterson was a controlling person of J&J through the majority of the Class Period, due to their senior executive positions with the Company and their direct involvement in the Company's day-to-day operations. By virtue of the foregoing, defendants Gorsky, Caruso, Sneed, and Peterson each had the power to influence and control, and did influence and control, directly or indirectly, the decision making of J&J, including the content of its public statements.

442. J&J had the power to control and influence the Individual Defendants and other Company executives through its Board of Directors and its power to hire, fire, supervise and otherwise control the actions of its employees and their salaries, bonuses, incentive compensation and other employment considerations. By virtue of the foregoing, J&J had the power to influence and control, and did influence and control, directly or indirectly, the decision making of the Individual Defendants, including the content of their public statements.

443. Defendants acted knowingly and intentionally, or in such a deliberately reckless manner as to constitute willful fraud and deceit upon plaintiff and the other members of the Class who purchased J&J common stock during the Class Period.

444. In ignorance of the false and misleading nature of the Company's statements and omissions, and relying directly or indirectly on those statements or

upon the integrity of the market prices for J&J common stock, plaintiff and other members of the Class purchased J&J securities at an artificially inflated price during the Class Period. But for the fraud, plaintiff and members of the Class would not have purchased J&J common stock at artificially inflated prices. As set forth herein, when the true facts were subsequently disclosed, the price of J&J common stock declined and plaintiff and members of the Class were harmed and damaged as a direct and proximate result of their purchases of J&J common stock at artificially inflated prices and the subsequent decline in the price of those securities when the truth began was disclosed.

445. By reason of the foregoing, defendants Gorsky, Caruso, Peterson, and Sneed are liable to plaintiff and the members of the Class as controlling persons of J&J in violation of §20(a) of the 1934 Act.

PRAYER FOR RELIEF

WHEREFORE, plaintiff prays for judgment as follows:

- A. Declaring this action to be a proper class action pursuant to Federal Rule of Civil Procedure 23;
- B. Awarding plaintiff and the members of the Class damages and interest;
- C. Awarding plaintiff's reasonable costs, including attorneys' fees; and
- D. Awarding such equitable/injunctive or other relief as the Court may deem just and proper.

JURY DEMAND

Plaintiff demands a trial by jury.

DATED: February 28, 2019

CARELLA, BYRNE, CECCHI, OLSTEIN,
BRODY & AGNELLO, P.C.
JAMES E. CECCHI

/s/ James E. Cecchi

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Lead Counsel for San Diego County
Employees Retirement Association and Lead
Counsel for the Class

EXHIBIT 1

CERTIFICATION PURSUANT TO FEDERAL SECURITIES LAWS

SAN DIEGO COUNTY EMPLOYEES RETIREMENT ASSOCIATION
("Plaintiff") declares:

1. Plaintiff has reviewed a complaint and authorized its filing. Plaintiff has authorized the filing of a motion for appointment as lead plaintiff.

2. Plaintiff did not acquire the security that is the subject of this action at the direction of plaintiff's counsel or in order to participate in this private action or any other litigation under the federal securities laws.

3. Plaintiff is willing to serve as a representative party on behalf of the class, including providing testimony at deposition and trial, if necessary.

4. Plaintiff has made the following transaction(s) during the Class Period in the securities that are the subject of this action:

<u>Security</u>	<u>Transaction</u>	<u>Date</u>	<u>Price Per Share</u>
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See attached Schedule A.

5. Plaintiff has not sought to serve or served as a representative party in a class action that was filed under the federal securities laws within the three-year period prior to the date of this Certification except as detailed below:

None.

6. Plaintiff will not accept any payment for serving as a representative party on behalf of the class beyond the Plaintiff's pro rata share of any recovery,

except such reasonable costs and expenses (including lost wages) directly relating to the representation of the class as ordered or approved by the court.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 27 day of February, 2019.

SAN DIEGO COUNTY EMPLOYEES
RETIREMENT ASSOCIATION

By: 

Brant Will, Chief Legal Officer

SCHEDULE A

SECURITIES TRANSACTIONS

Stock

<u>Date Acquired</u>	<u>Amount of Shares Acquired</u>	<u>Price</u>
06/26/2017	30,170	\$136.51
12/15/2017	24,144	\$142.46
05/08/2018	728	\$122.66
07/03/2018	2,409	\$122.74
<u>Date Sold</u>	<u>Amount of Shares Sold</u>	<u>Price</u>
02/20/2018	24,144	\$130.87
07/17/2018	1,061	\$128.74

EXHIBIT 2

DRAFT 1 – Copy for SafetyandCareCommitment Website

On Home Page of SafetyandCareCommitment.com website, at bottom right, under Key Topic, replace Microbeads with the following copy:

Key Topic

Talc has over 100 years of ~~safe~~ use in personal care products. Learn more ...

(Link to Ingredient Policies page, insert new item under “Other Materials” and after “Triclosan”, copy to read)

Talc

The Use of Cosmetic Talc in Personal Care Products

Few ingredients have demonstrated the same performance, mildness and safety profile as cosmetic talc, which has been used for over 100 ~~(I don’t think we can link cosmetic talc to 100 years of use)~~ years by millions of people around the world. Talcum powder is made from the mineral, talc. In a powder form, talc helps reduce friction, making it useful for keeping skin dry and helping to prevent rashes. Talc is a common ingredient found in cosmetic products such as baby powder and adult body and facial powders, and in a range of other consumer products such as toothpaste, chewing gum, and aspirin.

JOHNSON’S® talc products are made using U.S. Pharmacopeial (USP) grade talc to ensure it meets the highest-quality, purity and compliance standards. Our talc-based consumer products ~~are have always been~~ ~~(we cannot say “always”)~~ asbestos free, as confirmed by regular testing conducted since the 1970s. We also make JOHNSON’S® Baby Powder that contains cornstarch.

Our Position on Talc

At the Johnson & Johnson Family of Consumer Companies, our confidence in the using talc is based on a long history of safe use and more than 30 years of research by independent researchers, scientific review boards and global regulatory authorities. Various agencies and governmental bodies have examined whether talc is a carcinogen, and none have concluded that it is. These include the U.S Food and Drug Administration (FDA) and National Toxicology Program, part of the U.S. Department of Health and Human Services. California does not list cosmetic talc as a carcinogen under its Prop 65 list of substances identified as possible causes of cancer.

The Cosmetic Ingredient Review (CIR) is an independent scientific body that assesses the safety of ingredients and publishes results in peer-reviewed science journals. In April 2013 it published its most recent assessment of talc used in cosmetics. Its Expert Panel reviewed all information, data, studies spanning from 1976 through today, and concluded that talc was safe for use in personal care products. The U.S. FDA considers the CIR review, as well as other information, in policy making.

Various independent researchers have studied talc and perineal use and found it to be safe. A detailed meta-analysis done by Muscat/Huncharek in 2007, reviewed all available studies and showed no cause and effect relationship between perineal use and ovarian cancer. In 2011, Neill et al also was not able to find any association between perineal talc use and ovarian cancer. Publications based on the Nurses' Health Study, the only large-scale prospective study looking at talc and ovarian cancer, have found no causal relationship between talc and ovarian cancer (Gertig 2000; Gates 2009).

References and Resources:

NOTE TO CAROL/JAY: Besides those below, there are other links to consider, but they are not as definitive or supportive and could be interpreted as suggesting a causal effect, such as the American Cancer Society and IARC. Even some of the studies we cite send mixed messages. For example, Gertig et al concludes:

"Our results provide little support for any substantial association between perineal talc use and ovarian cancer risk overall; however, perineal talc use may modestly increase the risk of invasive serous ovarian cancers."

National Toxicology Program

<http://ntp.niehs.nih.gov/index.cfm?objectid=03CA6E02-FBD5-5C52-9699F9DD00863ED7>

Cosmetic Ingredient Review

http://www.cir-safety.org/sites/default/files/talc122012tent_faa_final%20for%20posting.pdf

Gertig, Prospective Study of Talc Use and Ovarian Cancer, *Journal of the National Cancer Institute*

<http://jnci.oxfordjournals.org/content/92/3/249.full>

Neill, Use of talcum powder and endometrial cancer risk, *Cancer Causes and Control*

<http://rd.springer.com/article/10.1007%2Fs10552-011-9894-5>

Muscat, Perineal talc use and ovarian cancer risk: a case study of scientific standards in environmental epidemiology, *European Journal of Cancer Prevention*

<http://www.ncbi.nlm.nih.gov/pubmed/21712717>

From Homer:

<http://www.fda.gov/Cosmetics/ProductandIngredientSafety/SelectedCosmeticIngredients/ucm293184.htm?source=govdelivery>

FDA sponsored a workshop in 1994 ("IS RTP/FDA Talc workshop"). I don't have a copy of the report but there are many references to the conclusions, such as those below. Experts agreed that there was no evidence to conclude that talc is capable of reaching the ovaries. And ... the experts attending the IS RTP/FDA Talc workshop concluded that the epidemiology studies did not demonstrate a real association between talc and ovarian cancer.

<http://www.cosmeticsinfo.org/HBI/26>

<http://www.thefactsabout.co.uk/content.asp?pageid=8&menuname=Talc&menu=hidden>

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EXHIBIT 3

Johnson & Johnson knew for decades that asbestos lurked in its Baby Powder

A REUTERS INVESTIGATION

REUTERS/Mike Wood

Facing thousands of lawsuits alleging that its talc caused cancer, J&J insists on the safety and purity of its iconic product. But internal documents examined by Reuters show that the company's powder was sometimes tainted with carcinogenic asbestos and that J&J kept that information from regulators and the public.

By [LISA GIRION](#) in Los Angeles | Filed Dec. 14, 2018, 2 p.m. GMT

Darlene Coker knew she was dying. She just wanted to know why.

She knew that her cancer, mesothelioma, arose in the delicate membrane surrounding her lungs and other organs. She knew it was as rare as it was deadly, a signature of exposure to asbestos. And she knew it afflicted mostly men who inhaled asbestos dust in mines and industries such as shipbuilding that used the carcinogen before its risks were understood.

Coker, 52 years old, had raised two daughters and was running a massage school in Lumberton, a small town in eastern Texas. How had she been exposed to asbestos? “She wanted answers,” her daughter Cady Evans said.

Fighting for every breath and in crippling pain, Coker hired Herschel Hobson, a personal-injury lawyer. He homed in on a suspect: the Johnson’s Baby Powder that Coker had used on her infant children and sprinkled on herself all her life. Hobson knew that talc and asbestos often occurred together in the earth, and that mined talc could be contaminated with the carcinogen. Coker [sued](#) Johnson & Johnson, alleging that “poisonous talc” in the company’s beloved product was her killer.



EARLY INDICATION: Cady Evans (left) and her sister, Crystal Deckard, surrounded by pictures of their mother, Darlene Coker, whose lawsuit against Johnson & Johnson 20 years ago was one of the first to allege that the company's Baby Powder caused cancer. REUTERS/Mike Blake

J&J didn't tell the FDA that at least three tests by three different labs from 1972 to 1975 had found asbestos in its talc – in one case at levels reported as “rather high.”

J&J [denied](#) the claim. Baby Powder was asbestos-free, it said. As the case proceeded, J&J was able to avoid handing over talc test results and other internal company records Hobson had requested to make the case against Baby Powder.

Coker had no choice but to drop her lawsuit, Hobson said. “When you are the plaintiff, you have the burden of proof,” he said. “We didn’t have it.”

That was in 1999. Two decades later, the material Coker and her lawyer sought is emerging as J&J has been compelled to share thousands of pages of company memos, internal reports and other confidential documents with lawyers for some of the 11,700 plaintiffs now claiming that the company's talc caused their cancers — including thousands of women with ovarian cancer.

A Reuters examination of many of those documents, as well as deposition and trial testimony, shows that from at least 1971 to the early 2000s, the company's raw talc and finished powders sometimes tested positive for small amounts of asbestos, and that company executives, mine managers, scientists, doctors and lawyers fretted over the problem and how to address it while failing to disclose it to regulators or the public.

The documents also depict successful efforts to influence U.S. regulators' plans to limit asbestos in cosmetic talc products and [scientific research](#) on the health effects of talc.

A small portion of the documents have been produced at trial and cited in media reports. Many were shielded from public view by court orders that allowed J&J to turn over thousands of documents it designated as confidential. Much of their contents is reported here for the first time.

The earliest mentions of tainted J&J talc that Reuters found come from 1957 and 1958 [reports](#) by a consulting lab. They describe contaminants in talc from J&J's Italian supplier as

RELATED CONTENT

fibrous and “acicular,” or needle-like, tremolite. That’s one of the six minerals that in their naturally occurring fibrous form are classified as asbestos.

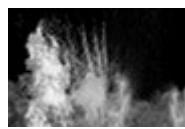
At various times from then into the early 2000s, reports by scientists at J&J, outside labs and J&J’s supplier yielded similar findings. The [reports](#) identify contaminants in talc and finished powder products as asbestos or describe them in terms typically applied to asbestos, such as “fiberform” and “rods.”

In 1976, as the U.S. Food and Drug Administration (FDA) was weighing limits on asbestos in cosmetic talc products, J&J [assured the regulator](#) that no asbestos was “detected in any sample” of talc produced between December 1972 and October 1973. It didn’t tell the agency that at least three [tests](#) by three different labs from 1972 to 1975 had found asbestos in its talc – in one case at levels reported as “[rather high](#).”

Most internal J&J asbestos test reports Reuters reviewed do not find asbestos. However, while J&J’s testing methods improved over time, they have always had limitations that allow trace contaminants to go undetected – and only a [tiny fraction](#) of the company’s talc is tested.

The World Health Organization and other authorities recognize no safe level of exposure to asbestos. While most people exposed never develop cancer, for some, even small amounts of asbestos are enough to trigger the disease years later. Just how small hasn’t been established. Many plaintiffs allege that the amounts they inhaled when they dusted themselves with tainted talcum powder were enough.

The evidence of what J&J knew has surfaced after people who suspected that talc caused their cancers hired lawyers experienced in the decades-long deluge of litigation involving workers exposed to asbestos. Some of the lawyers knew from those earlier cases that talc producers tested for asbestos, and they began demanding J&J’s testing documentation.



A guiding hand on talc safety research



Read the documents cited in this article



After damaging Reuters report, J&J doubles down on talc safety message

0:00 / 7:44

■ A big verdict fuels a reporter’s curiosity. REUTERS/Mike Wood

What J&J produced in response to those demands has allowed plaintiffs’ lawyers to refine their argument: The culprit wasn’t necessarily talc itself, but also asbestos in the talc. That assertion, backed by decades of solid science showing that asbestos causes mesothelioma and is associated with ovarian and other cancers, has had mixed success in court.

In two cases earlier this year – in New Jersey and California – juries awarded big sums to plaintiffs who, like Coker, blamed asbestos-tainted J&J talc products for their mesothelioma.

A third verdict, in St. Louis, was a watershed, broadening J&J’s potential liability: The 22 plaintiffs were the first to succeed with a claim that asbestos-tainted Baby Powder and Shower to Shower talc, a longtime brand the company sold in 2012, caused ovarian cancer, which is much more common than mesothelioma. The jury awarded them \$4.69 billion in damages. Most of the talc cases



have been brought by women with ovarian cancer who say they regularly used J&J talc products as a perineal antiperspirant and deodorant.

At the same time, at least three juries have rejected claims that Baby Powder was tainted with asbestos or caused plaintiffs' mesothelioma. Others have failed to reach verdicts, resulting in mistrials.

J&J has said it will appeal the recent verdicts against it. It has maintained in public statements that its talc is safe, as shown for years by the best tests available, and that the information it has been required to divulge in recent litigation shows the care the company takes to ensure its products are asbestos-free. It has blamed its losses on juror confusion, "junk" science, unfair court rules and overzealous lawyers looking for a fresh pool of asbestos plaintiffs.

"Plaintiffs' attorneys out for personal financial gain are distorting historical documents and intentionally creating confusion in the courtroom and in the media," Ernie Knewitz, J&J's vice president of global media relations, wrote in an emailed response to Reuters' findings. "This is all a calculated attempt to distract from the fact that thousands of independent tests prove our talc does not contain asbestos or cause cancer. Any suggestion that Johnson & Johnson knew or hid information about the safety of talc is false."

J&J declined to comment further for this article. For more than two months, it turned down repeated requests for an interview with J&J executives. On Dec. 8, the company offered to make an expert available. It had not done so as of Thursday evening.

The company referred all inquiries to its outside litigation counsel, Peter Bicks. In emailed responses, Bicks rejected Reuters' findings as "false and misleading." "The scientific consensus is that the talc used in talc-based body powders does not cause cancer, regardless of what is in that talc," Bicks wrote. "This is true even if - and it does not - Johnson & Johnson's cosmetic talc had ever contained minute, undetectable amounts of asbestos." He dismissed tests cited in this article as "outlier" results.

In court, J&J lawyers have told jurors that company records showing that asbestos was detected in its talc referred to talc intended for industrial use. Other records, they have argued, referred to non-asbestos forms of the same minerals that their experts say are harmless. J&J has also argued that some tests picked up "background" asbestos – stray fibers that could have contaminated samples after floating into a mill or lab from a vehicle clutch or fraying insulation.

The company has made some of the same arguments about lab tests conducted by experts hired by plaintiffs. One of those labs found asbestos in Shower to Shower talc from the 1990s, according to an Aug. 11, 2017, court report. Another lab found asbestos in more than half of multiple samples of Baby Powder from past decades – in bottles from plaintiffs' cupboards and acquired from eBay, and even a [1978 bottle](#) held in J&J's corporate museum. The concentrations were great enough that users "would have, more likely than not, been exposed," the plaintiffs' lab report presented in several cases this year concluded.

Matthew Sanchez, a geologist with consultants RJ Lee Group Inc and a frequent expert witness for J&J, dismissed those findings in testimony in the St. Louis trial: "I have not found asbestos in any of the current or modern, what I consider modern, Johnson & Johnson talc products," Sanchez told the jury.

Sanchez did not return calls seeking comment. RJ Lee said it does not comment on the work it does for clients.

Since 2003, talc in Baby Powder sold in the United States has come from China through supplier Imerys Talc America, a unit of Paris-based Imerys SA and a co-defendant in most of the talc litigation. Imerys and J&J said the Chinese talc is safe. An Imerys spokesman said the company's tests "consistently show no asbestos. Talc's safe use has been confirmed by multiple regulatory and scientific bodies."

J&J, based in New Brunswick, New Jersey, has dominated the talc powder market for more than 100 years, its sales outpacing those of all competitors combined, according to Euromonitor International data. And while talc products contributed just \$420 million to J&J's \$76.5 billion in revenue last year, Baby Powder is considered an essential facet of the healthcare-products maker's carefully tended image as a caring company – a "sacred cow," as one 2003 internal email put it.

"When people really understand what's going on, I think it increases J&J's exposure a thousand-fold," said Mark Lanier, one of the lawyers for the women in the St. Louis case.

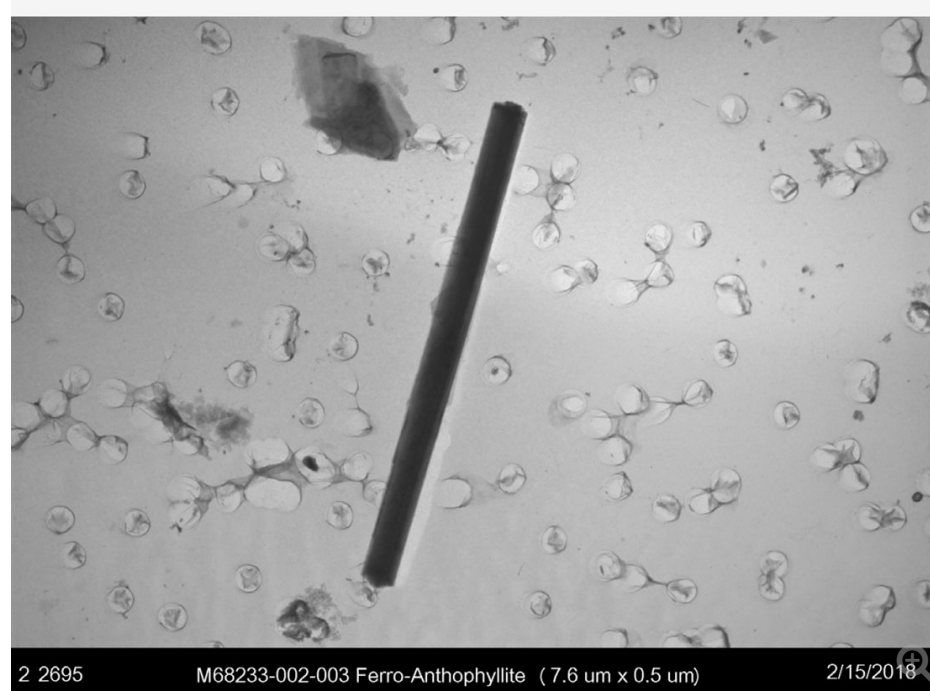
The mounting controversy surrounding J&J talc hasn't shaken investors. The share price is up about 6 percent so far this year. Talc cases make up fewer than 10 percent of all personal injury lawsuits pending against J&J, based on the company's Aug. 2 quarterly report, in which the company said it believed it had "strong grounds on appeal."

J&J Chairman and Chief Executive Officer Alex Gorsky has pledged to fight on, telling analysts in July: "We remain confident that our products do not contain asbestos."

Gorsky's comment, echoed in countless J&J statements, misses a crucial point. Asbestos, like many environmental carcinogens, has a long latency period. Diagnosis usually comes years after initial exposure – 20 years or longer for mesothelioma. J&J talc products today may be safe, but the talc at issue in thousands of lawsuits was sold and used over the past 60 years.

That point is recognized in a 2013 [markup](#) of a statement for the “Safety & Care Commitment” page of J&J’s website. The original version conveyed a blanket assurance of safety. The edited version was less definitive: “Our talc-based consumer products ~~are have always been~~ (we cannot say “always”) asbestos free, as confirmed by regular testing since the 1970s.”

2013



NEEDLES IN A HAYSTACK: Bundles (top, center) and a single fiber (bottom) that a plaintiffs’ lab found in a 1978 bottle of Baby Powder from J&J’s corporate museum show the telltale needle-like shape of asbestos. Photo courtesy of Mark Lanier.

JOHNSON’S® talc products are made using U.S. Pharmacopeial (USP) grade talc to ensure it meets the highest-quality, purity and compliance standards. Our talc-based consumer products ~~are have always been~~ (we cannot say “always”) asbestos free, as confirmed by regular testing conducted since the 1970s. We also make JOHNSON’S® Baby Powder that contains cornstarch.

THEN AND NOW: A 2013 markup of a statement for J&J’s website implicitly recognizes the possibility that the company’s talc could have been tainted in earlier times.

“Safety first”

In 1886, Robert Wood Johnson enlisted his younger brothers in an eponymous startup built around the “Safety First” motto. Johnson’s Baby Powder grew out of a line of medicated plasters, sticky rubber strips loaded with mustard and other home remedies. When customers complained of skin irritation, the brothers sent packets of talc.

Soon, mothers began applying the talc to infants’ diaper-chafed skin. The Johnsons took note. They added a fragrance that would become one of the most recognizable in the world, sifted the talc into tin boxes and, in 1893, began selling it as Johnson’s Baby Powder.

In the late 1950s, J&J discovered that talc from its chief source mine for the U.S. market in the Italian Alps contained tremolite. That’s one of six minerals – along with chrysotile, actinolite, amosite, anthophyllite and crocidolite – that occur in nature as crystalline fibers known as asbestos, a recognized carcinogen. Some of them, including tremolite, also occur as unremarkable “non-asbestiform” rocks. Both forms often occur together and in talc deposits.

J&J’s worry at the time was that contaminants made the company’s powder abrasive. It sent tons of its Italian talc to a private lab in Columbus, Ohio, to find ways to improve the appearance, feel and purity of the powder by removing as much “grit” as possible. In a pair of [reports](#) from 1957 and 1958, the lab said the talc contained “from less than 1 percent to about 3 percent of contaminants,” described as mostly fibrous and “acicular” tremolite.

Most of the authors of these and other J&J records cited in this article are dead. Sanchez, the RJ Lee geologist whose firm has agreed to provide him as a witness in up to 100 J&J talc trials, has testified that tremolite found decades ago in the company’s talc, from Italy and later Vermont, was not tremolite asbestos at all. Rather, he has said, it was “cleavage fragments” from non-asbestiform tremolite.

J&J’s original records don’t always make that distinction. In terms of health risk, regulators since the early 1970s have treated small fiber-shaped particles of both forms the same.

The U.S. Environmental Protection Agency, for example, “makes no distinction between fibers and (comparable) cleavage fragments,” agency officials [wrote](#) in a response to an RJ Lee report on an unrelated matter in 2006, the year before the firm hired Sanchez. The Occupational Safety and Health Administration (OSHA), though it dropped the non-fibrous forms of the minerals from its definition of asbestos in 1992, nonetheless [recommends](#) that fiber-shaped fragments indistinguishable from asbestos be counted in its exposure tests.

And as the product safety director for J&J’s talc supplier acknowledged in a 2008 email to colleagues: “(I)f a deposit contains ‘non-asbestiform’ tremolite, there is also asbestiform tremolite naturally present as well.”



“SACRED COW”: Today, Baby Powder accounts for only a small portion of J&J’s annual revenue, but is considered essential to the company’s caring image. REUTERS/Mike Segar

“The lungs of babies”

In 1964, J&J's Windsor Minerals Inc subsidiary bought a cluster of talc mines in Vermont, with names like Argonaut, Rainbow, Frostbite and Black Bear. By 1966, it was blasting and bulldozing white rock out of the Green Mountain state. J&J used the milled powder in its cosmetic powders and sold a less-refined grade to roofing, flooring and tire companies for use in manufacturing.

Ten years after tremolite turned up in the Italian talc, it showed up in Vermont talc, too. In 1967, J&J found traces of tremolite and another mineral that can occur as asbestos, according to a table attached to a Nov. 1, 1967, [memo](#) by William Ashton, the executive in charge of J&J's talc supply for decades.

J&J continued to search for sources of clean talc. But in an April 9, 1969, [memo](#) to a company doctor, Ashton said it was "normal" to find tremolite in many U.S. talc deposits. He suggested J&J rethink its approach. "Historically, in our Company, Tremolite has been bad," Ashton wrote. "How bad is Tremolite medically, and how much of it can safely be in a talc base we might develop?"

Since pulmonary disease, including cancer, appeared to be on the rise, "it would seem to be prudent to limit any possible content of Tremolite ... to an absolute minimum," came the [reply](#) from another physician executive days later.

The doctor told Ashton that J&J was receiving safety questions from pediatricians. Even Robert Wood Johnson II, the founder's son and then-retired CEO, had expressed "concern over the possibility of the adverse effects on the lungs of babies or mothers," he wrote.

"We have replied," the doctor wrote, that "we would not regard the usage of our powders as presenting any hazard." Such assurances would be impossible, he added, "if we do include Tremolite in more than unavoidable trace amounts."

The memo is the earliest J&J document reviewed by Reuters that discusses tremolite as more than a scratchy nuisance. The doctor urged Ashton to consult with company lawyers because "it is not inconceivable that we could become involved in litigation."

Never "100% clean"

By the early 1970s, asbestos was widely recognized as the primary cause of mesothelioma among workers involved in producing it and in industries that used it in their products.

Regulation was in the air. In 1972, President Richard Nixon's newly created OSHA issued its first rule, setting limits on workplace exposure to asbestos dust.

By then, a team at Mount Sinai Medical Center led by pre-eminent asbestos researcher Irving Selikoff had started looking at talcum powders as a possible solution to a puzzle: Why were tests of lung tissue taken post mortem from New Yorkers who never worked with asbestos finding signs of the mineral? Since talc deposits are often laced with asbestos, the scientists reasoned, perhaps talcum powders played a role.

They shared their preliminary findings with New York City's environmental protection chief, Jerome Kretchmer. On June 29, 1971, Kretchmer informed the Nixon administration and called a press conference to announce that two unidentified brands of cosmetic talc appeared to contain asbestos.

The FDA opened an inquiry. J&J issued a [statement](#): "Our fifty years of research knowledge in this area indicates that there is no asbestos contained in the powder manufactured by Johnson & Johnson."

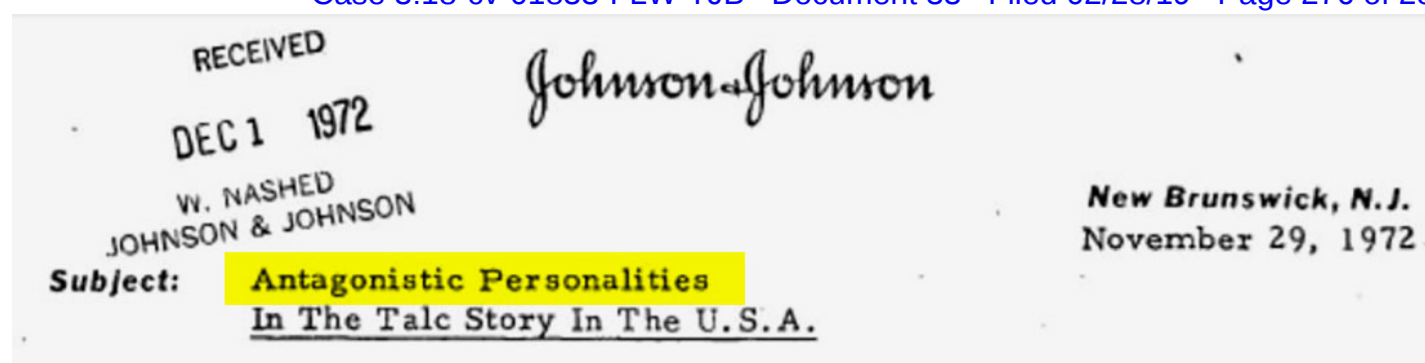
Later that year, another Mount Sinai researcher, mineralogist Arthur Langer, told J&J in a [letter](#) that the team had found a "relatively small" amount of chrysotile asbestos in Baby Powder.



ROCK STEADY: Dr Arthur Langer, who was part of a Mount Sinai team researching asbestos in talc in the 1970s, says he stands by his finding of small amounts of asbestos in Baby Powder. REUTERS/Julia Rendleman



SPREADING THE WORD: Jerome Kretchmer was New York City's environmental protection chief when he announced that the Mount Sinai research team had found what appeared to be asbestos in two unidentified brands of cosmetic talc. REUTERS/Jeenah Moon



NOTORIETY: Langer and Kretchmer ended up on an internal J&J list of “antagonistic personalities.”

Langer, Selikoff and Kretchmer ended up on a J&J list of “antagonistic personalities” in a Nov. 29, 1972, [memo](#), which described Selikoff as the leader of an “attack on talc.”

“I suppose I was antagonistic,” Langer told Reuters. Even so, in a subsequent test of J&J powders in 1976, he didn’t find asbestos – a result that Mount Sinai [announced](#).

Langer said he told J&J lawyers who visited him last year that he stood by all of his findings. J&J has not called him as a witness.

Selikoff died in 1992. Kretchmer said he recently read that a jury had concluded that Baby Powder was contaminated with asbestos. “I said to myself, ‘How come it took so long?’ ” he said.

In July 1971, meanwhile, J&J sent a delegation of scientists to Washington to talk to the FDA officials looking into asbestos in talcum powders. According to an FDA [account](#) of the meeting, J&J shared “evidence that their talc contains less than 1%, if any, asbestos.”

Later that month, Wilson Nashed, one of the J&J scientists who visited the FDA, said in a [memo](#) to the company’s public relations department that J&J’s talc contained trace amounts of “fibrous minerals (tremolite/actinolite).”

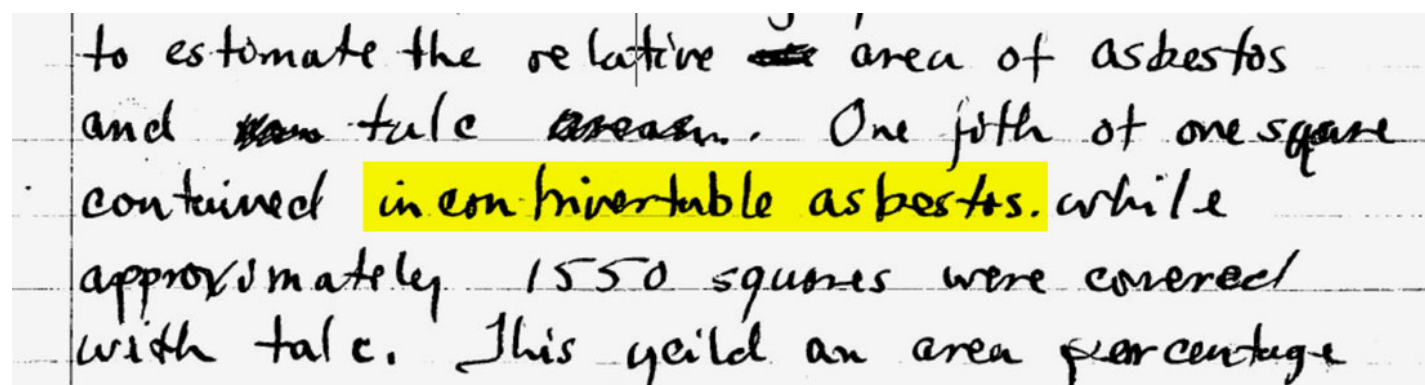
As the FDA continued to investigate asbestos in talc, J&J sent [powder samples](#) to be tested at private and university labs. Though a private lab in Chicago found trace amounts of tremolite, it [declared](#) the amount “insignificant” and the samples “substantially free of asbestiform material.” J&J reported that finding to the FDA under a cover letter that said the “results clearly show” the samples tested “contain no chrysotile asbestos.” J&J’s lawyer told Reuters the tremolite found in the samples was not asbestos.



TOP TESTER: Irving Selikoff, who led the Mount Sinai team that investigated asbestos and talc, was also listed among J&J’s “antagonistic personalities.” Photo courtesy of Arthur Langer

But J&J’s FDA submission left out University of Minnesota professor Thomas E. Hutchinson’s finding of chrysotile in a Shower to Shower sample – “incontrovertible asbestos,” as he described it in a [lab note](#).

1972



NO DOUBT: In a lab note, a University of Minnesota professor recorded finding “incontrovertible asbestos” in a sample of J&J’s Shower to Shower talc.

The FDA’s own examinations found no asbestos in J&J powder samples in the 1970s. Those tests, however, did not use the most sensitive detection methods. An early test, for example, was incapable of detecting chrysotile fibers, as an FDA official recognized in a J&J account of an Aug. 11, 1972, meeting with the agency: “I understand that some samples will be passed even though they contain such fibers, but we are willing to live with it.”

By 1973, Tom Shelley, director of J&J’s Central Research Laboratories in New Jersey, was looking into acquiring patents on a process that a British mineralogist and J&J consultant was developing to separate talc from tremolite.

“It is quite possible that eventually tremolite will be prohibited in all talc,” Shelley [wrote](#) on Feb. 20, 1973, to a British colleague. Therefore, he added, the “process may well be valuable property to us.”

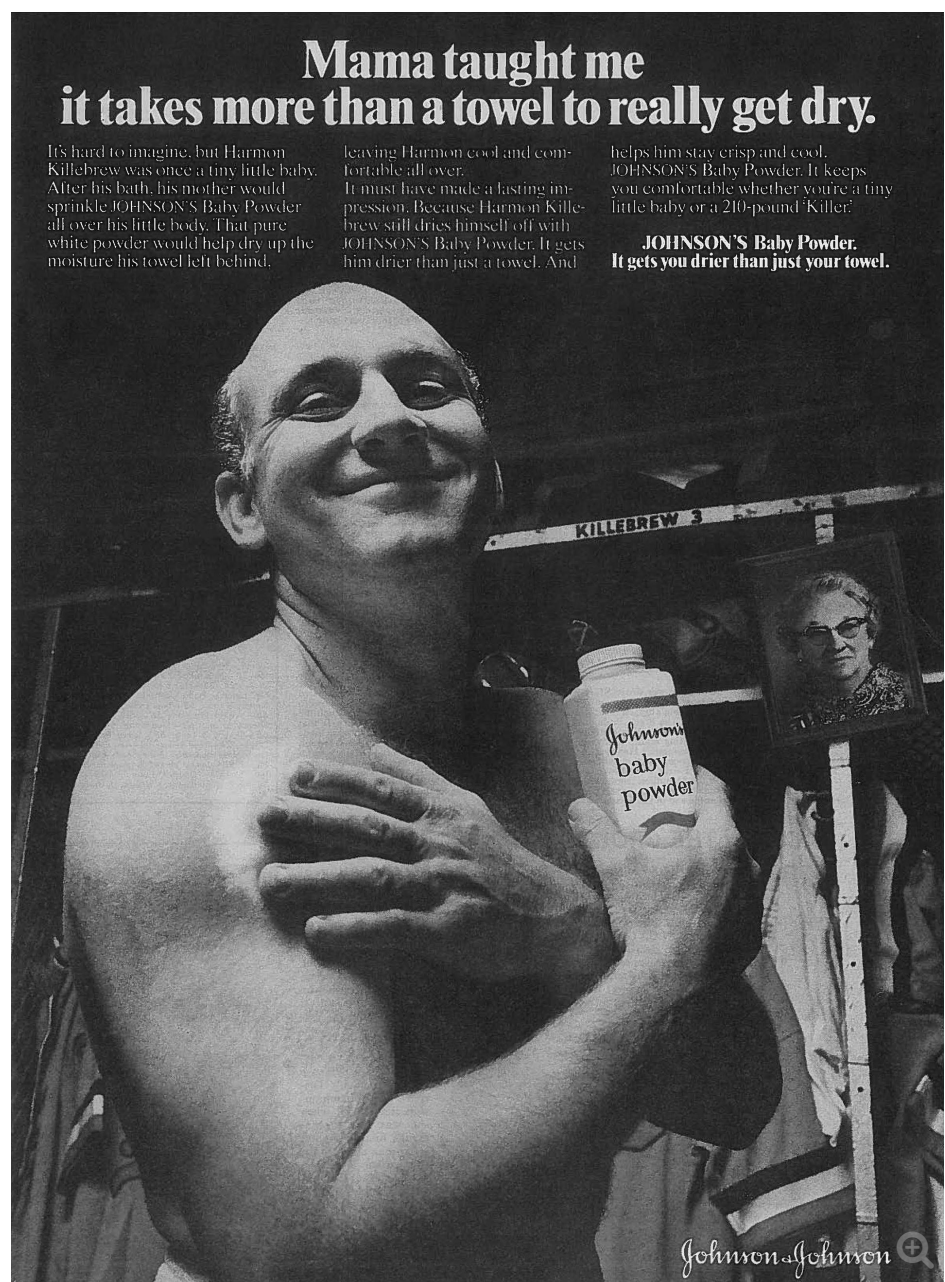
At the end of March, Shelley recognized the sensitivity of the plan in a [memo](#) sent to a J&J lawyer in New Jersey: “We will want to carefully consider the ... patents re asbestos in talc. It’s quite possible that we may wish to keep the whole thing confidential rather than allow it to be published in patent form and thus let the whole world know.”

J&J did not obtain the patents.

While Shelley was looking into the patents, J&J research director DeWitt Petterson visited the company’s Vermont mining operation. “Occasionally, sub-trace quantities of tremolite or actinolite are identifiable,” he wrote in an April 1973 [report](#) on the visit. “And these might be classified as asbestos fiber.”

J&J should “protect our powder franchise” by eliminating as many tiny fibers that can be inhaled in airborne talc dust as possible, Petterson wrote. He warned, however, that “no final product will ever be made which will be totally free from respirable particles.” Introducing a cornstarch version of Baby Powder, he noted, “is obviously another answer.”

1973



1972: Baseball Hall of Fame slugger Harmon Killebrew plugs Baby Powder.

undertaken with a good chance of success in this area. It should be cautioned, however, that **no final product will ever be made which will be totally free from respirable particles.** We are talking about a significant reduction in fine particle count but not 100% clean-up.

UNACHIEVABLE: J&J research director DeWitt Petterson warned the company that producing pure talc was impossible.

Bicks told Reuters that J&J believes that the tremolite and actinolite Petterson cited were not asbestos.

Cornstarch came up again in a March 5, 1974, [report](#) in which Ashton, the J&J talc supply chief, recommended that the company research that alternative “for defensive reasons” because “the thrust against talc has centered primarily on biological problems alleged to result from the inhalation of talc and related mineral particles.”

“We may have problems”

A few months after Petterson’s recognition that talc purity was a pipe dream, the FDA proposed a rule that talc used in drugs contain no more than 0.1 percent asbestos. While the agency’s cosmetics division was considering similar action on talcum powders, it asked companies to suggest testing methods.

At the time, J&J’s Baby Powder franchise was consuming 20,000 tons of Vermont talc a year. J&J [pressed](#) the FDA to approve an X-ray scanning [technique](#) that a company scientist said in an April 1973 memo allowed for “an automatic 1% tolerance for asbestos.” That would mean talc with up to 10 times the FDA’s proposed limit for asbestos in drugs could pass muster.

The same scientist confided in an Oct. 23, 1973, [note](#) to a colleague that, depending on what test the FDA adopted for detecting asbestos in cosmetic talc, “we may have problems.”

The best way to detect asbestos in talc was to concentrate the sample and then examine it through microscopes, the Colorado School of Mines Research Institute told J&J in a Dec. 27, 1973, [report](#). In a [memo](#), a J&J lab supervisor said the concentration technique, which the company’s own researchers had earlier used to identify a “tremolite-type” asbestos in Vermont talc, had one limitation: “It may be too sensitive.”

“No mother was going to powder her baby with 1% of a known carcinogen irregardless of the large safety factor.”

An FDA official commenting in 1975 on the talc testing method J&J backed

In his email to Reuters, J&J’s lawyer said the lab supervisor’s concern was that the test would result in “false positives,” showing asbestos where there was none.

J&J also launched [research](#) to find out how much powder a baby was exposed to during a diapering and how much asbestos could be in that powder and remain within OSHA’s new workplace exposure [limits](#). Its researchers had strapped an air sampling device to a doll to take measurements while it was powdered, according to J&J memos and the minutes of a Feb. 19, 1974, meeting of the Cosmetic Toiletry and Fragrance Association (CTFA), an industry group.

“It was calculated that even if talc were pure asbestos the levels of exposure of a baby during a normal powdering are far below the accepted tolerance limits,” the minutes state.

In a Sept. 6, 1974, [letter](#), J&J told the FDA that since “a substantial safety factor can be expected” with talc that contains 1 percent asbestos, “methods capable of determining less than 1% asbestos in talc are not necessary to assure the safety of cosmetic talc.”

Not everyone at the FDA thought that basing a detection method on such a calculation was a good idea. One official called it “foolish,” adding, according to a J&J [account](#) of a February 1975 meeting: “No mother was going to powder her baby with 1% of a known carcinogen irregardless of the large safety factor.”

“Misrepresentation by omission”

Having failed to persuade the FDA that up to 1 percent asbestos contamination was tolerable, J&J began promoting self-policing as an alternative to regulation. The centerpiece of this approach was a March 15, 1976, package of letters from J&J and other manufacturers that the CTFA gave to the agency to show that they had succeeded at eliminating asbestos from cosmetic talc.

“The attached letters demonstrate responsibility of industry in monitoring its talcs,” the [cover letter](#) said. “We are certain that the summary will give you assurance as to the freedom from contamination by asbestos for materials of cosmetic talc products.”

In its [letter](#), J&J said samples of talc produced between December 1972 and October 1973 were tested for asbestos, and none was detected “in any sample.”

J&J didn’t tell the FDA about a 1974 [test](#) by a professor at Dartmouth College in New Hampshire that turned up asbestos in talc from J&J – “fiberform” actinolite, as he put it. Nor did the company tell the FDA about a 1975 report from its longtime lab that found particles identified as “asbestos fibers” in five of 17 samples of talc from the chief source mine for Baby Powder. “Some of them seem rather high,” the private lab wrote in its [cover letter](#).

Bicks, the J&J lawyer, said the contract lab’s results were irrelevant because the talc was intended for industrial use. He said the company now believes that the actinolite the Dartmouth professor found “was not asbestiform,” based on its interpretation of a [photo](#) in the original lab report.

Just two months after the Dartmouth professor reported his findings, Windsor Minerals Research and Development Manager Vernon Zeitz wrote that chrysotile, “fibrous anthophyllite” and other types of asbestos had been “found in association with the Hammondsville ore body” – the Vermont deposit that supplied Baby Powder talc for more than two decades.



FOR EVERYONE: For decades, J&J has promoted its iconic Baby Powder as a safe, gentle product for babies and adults alike.

Zeitz's May 1974 [report](#) on efforts to minimize asbestos in Vermont talc "strongly urged" the adoption of ways to protect "against what are currently considered to be materials presenting a severe health hazard and are potentially present in all talc ores in use at this time."

Bicks said that Zeitz was not reporting on actual test results.

The following year, Zeitz [reported](#) that based on weekly tests of talc samples over six months, "it can be stated with a greater than 99.9% certainty that the ores and materials produced from the ores at all Windsor Mineral locations are free from asbestos or asbestiform minerals."

J&J's selective use of test results figured in a New Jersey judge's decision this year to affirm the first verdict against the company in a case claiming asbestos in J&J products caused cancer. "Providing the FDA favorable results showing no asbestos and withholding or failing to provide unfavorable results, which show asbestos, is a form of a misrepresentation by omission," Middlesex County Superior Court Judge Ana Viscomi said in her June [ruling](#).

"J&J respectfully disagrees with the Judge's comments," Bicks said. "J&J did not withhold any relevant testing from FDA."

The FDA declined to comment on the ruling.

Lacking consensus on testing methods, the FDA postponed action to limit asbestos in talc. Years later, it did set limits on asbestos in talc used in drugs. It has never limited asbestos in cosmetic talc or established a preferred method for detecting it.

Instead, in 1976, a CTFA committee chaired by a J&J executive drafted voluntary [guidelines](#), establishing a form of X-ray scanning with a 0.5 percent detection limit as the primary test, the method J&J preferred. The method is not designed to detect the most commonly used type of asbestos, chrysotile, at all. The group said the more sensitive electron microscopy was impractical.

The CTFA, which now does business as the Personal Care Products Council, declined to comment.

X-ray scanning is the primary [method](#) J&J has used for decades. The company also periodically requires the more sensitive checks with electron microscopes. J&J's lawyer said the company's tests exceed the trade association standard, and they do. He also said that today, J&J's X-ray scans can detect suspect minerals at levels as low as 0.1 percent of a sample.

But the company never adopted the Colorado lab's 1973 [recommendation](#) that samples be concentrated before examination under a microscope. And the talc samples that were subjected to the most sensitive electron microscopy test were a tiny fraction of what was sold. For those and other reasons, J&J couldn't guarantee its Baby Powder was asbestos-free when plaintiffs used it, according to experts, including some who testified for plaintiffs.

As early as 1976, Ashton, J&J's longtime talc overseer, recognized as much in a [memo](#) to colleagues. He wrote that talc in general, if subjected to the most sensitive testing method, using concentrated samples, "will be hard pressed in supporting purity claims." He described this sort of testing as both "sophisticated" and "disturbing."

By 1977, J&J appeared to have tamped down concerns about the safety of talc. An internal August [report](#) on J&J's "Defense of Talc Safety" campaign noted that independent authorities had deemed cosmetic talc products to be "free of hazard." It attributed "this growing opinion" to the dissemination to scientific and medical communities in the United States and Britain of "favorable data from the various J&J sponsored studies."

In 1984, FDA cosmetics chief and former J&J employee Heinz Eiermann reiterated that view. He told the New York Times that the agency's investigation a decade earlier had prompted the industry to ensure that talc was asbestos-free. "So in subsequent analyses," he told the paper, "we really could not identify asbestos or only on very rare occasions."

Two years later, the FDA rejected a citizen request that cosmetic talc carry an asbestos warning label, saying that even if there were trace contamination, the use of talc powder during two years of normal diapering would not increase the risk of cancer.

In 1980, J&J began offering a cornstarch version of Baby Powder – to expand its customer base to people who prefer cornstarch, the company says.



Actress Blair Brown touts Baby Powder in this 1970s-era TV commercial

The persistence of the industry's view that cosmetic talc is asbestos-free is why no studies have been conducted on the incidence of mesothelioma among users of the products. It's also partly why regulations that protect people in mines, mills, factories and schools from asbestos-laden talc don't apply to babies and others exposed to cosmetic talc – even though Baby Powder talc has at times come from the same mines as talc sold for industrial use. J&J says cosmetic talc is more thoroughly processed and thus purer than industrial talc.

Until recently, the American Cancer Society (ACS) accepted the industry's position, saying on its website: "All talcum products used in homes have been asbestos-free since the 1970s."

After receiving inquiries from Reuters, the ACS in early December [revised its website](#) to remove the assurance that cosmetic talcs are free of asbestos. Now, it says, quoting the industry's standards, that all cosmetic talc products in the United States "should be free from detectable amounts of asbestos."

The revised ACS [web page](#) also notes that the World Health Organization's International Agency for Research on Cancer [classifies](#) talc that contains asbestos as "carcinogenic to humans."

Despite the success of J&J's efforts to promote the safety of its talc, the company's test lab found asbestos fibers in samples taken from the Vermont operation in [1984](#), [1985](#) and [1986](#). Bicks said: "The samples that we know of during this time period that contained a fiber or two of asbestos were not cosmetic talc samples."

Then, in 1992, three years after J&J sold its Vermont mines, the new owner, Cyprus Minerals, said in an internal [report](#) on "important environmental issues" in its talc reserves that there was "past tremolite" in the Hammondsville deposit. Hammondsville was the primary source of Baby Powder talc from 1966 until its shutdown in 1990.

Bicks rejected the Cyprus report as hearsay, saying there is no original documentation to confirm it. Hammondsville mine records, according to a 1993 J&J [memo](#), "were destroyed by the mine management staff just prior to the J&J divestiture."

Bicks said the destroyed documents did not include talc testing records.

1993

***(Note- The specifics of the mining operation at Hammondsville are uncertain, as most of the pre-Luzenac records were destroyed by the mine management staff just prior to the J&J divestiture and the Cyprus purchase. However, several former Hammondsville miners are still employed at the Ham mine, and they provided us with useful information as to the nature of the underground works.)**

MISSING: A J&J memo reveals that records of the Hammondsville mine, the main source of Baby Powder talc from 1966 until 1990, were destroyed by mine managers while J&J still owned the business.

In 2002 and 2003, Vermont mine operators found chrysotile asbestos fibers on several occasions in talc produced for Baby Powder sold in Canada. In each case, a single fiber was recorded – a [finding](#) deemed "BDL" – below detection limit. Bicks described the finding as "background asbestos" that did not come from any talc source.

In 2009, the FDA, responding to growing public concern about talc, commissioned tests on 34 samples, including a bottle of J&J Baby Powder and samples of Imerys talc from China. No asbestos was detected.

FDA Commissioner Scott Gottlieb said the agency continues to receive a lot of questions about talc cosmetics. "I recognize the concern," he told Reuters. He said the agency's policing of cosmetics in general – fewer than 30 people regulating a "vast" industry – was "a place where we think we can be doing more."

Gottlieb said the FDA planned to host a public forum in early 2019 to “look at how we would develop standards for evaluating any potential risk.” An agency spokeswoman said that would include examining “scientific test methods for assessment of asbestos.”

“Fishing expedition”

Before law school, Herschel Hobson worked at a rubber plant. There, his job included ensuring that asbestos in talc the workers were exposed to didn’t exceed OSHA limits.

That’s why he zeroed in on Johnson’s Baby Powder after he took on Darlene Coker as a client in 1997. The [lawsuit](#) Coker and her husband, Roy, filed that year against J&J in Jefferson County District Court in Beaumont, Texas, is the earliest Reuters found alleging Baby Powder caused cancer.

Hobson asked J&J for any research it had into the health of its mine workers; talc production records from the mid-1940s through the 1980s; depositions from managers of three labs that tested talc for J&J; and any documents related to testing for fibrous or asbestiform materials.

J&J [objected](#). Hobson’s “fishing expedition” would not turn up any relevant evidence, it asserted in a May 6, 1998, motion. In fact, among the thousands of documents Hobson’s request could have turned up was a [letter](#) J&J lawyers had received only weeks earlier from a Rutgers University geologist confirming that she had found asbestos in the company’s Baby Powder, identified in her 1991 published study as tremolite “asbestos” needles.

Hobson agreed to [postpone](#) his discovery demands until he got the pathology report on Coker’s lung tissue. Before it came in, J&J asked the judge to [dismiss](#) the case, arguing that Coker had “no evidence” Baby Powder caused mesothelioma.

Ten days later, the [pathology report](#) landed: Coker’s lung tissue contained tens of thousands of “long fibers” of four different types of asbestos. The findings were “consistent with exposure to talc containing chrysotile and tremolite contamination,” the report concluded.

“The asbestos fibers found raise a new issue of fact,” Hobson told the judge in a [request](#) for more time to file an opposition to J&J’s dismissal motion. The judge gave him more time but [turned down](#) his request to resume discovery.

Without evidence from J&J and no hope of ever getting any, Hobson advised Coker to [drop](#) the suit.

Hobson is still practicing law in Nederland, Texas. When Reuters told him about the evidence that had emerged in recent litigation, he said: “They knew what the problems were, and they hid it.” J&J’s records would have made a “100% difference” in Coker’s case.

Had the information about asbestos in J&J’s talc come out earlier, he said, “maybe there would have been 20 years less exposure” for other people.

Bicks, the J&J lawyer, said Coker dropped her case because “the discovery established that J&J talc had nothing to do with Plaintiff’s disease, and that asbestos exposure from a commercial or occupational setting was the likely cause.”

Coker never learned why she had mesothelioma. She did beat the odds, though. Most patients die within a year of diagnosis. Coker held on long enough to see her two grandchildren. She died in 2009, 12 years after her diagnosis, at age 63.

Coker’s daughter Crystal Deckard was 5 when her sister, Cady, was born in 1971. Deckard remembers seeing the white bottle of Johnson’s Baby Powder on the changing table where her mother diapered her new sister.

“When Mom was given this death sentence, she was the same age as I am right now,” Deckard said. “I have it in the back of my mind all the time. Could it happen to us? Me? My sister?”



NO SATISFACTION: Lacking the evidence she needed, Darlene Coker, here with one of her doctors, died without ever finding out what caused her mesothelioma. Cady Evans/Handout via REUTERS

A guiding hand on talc safety research

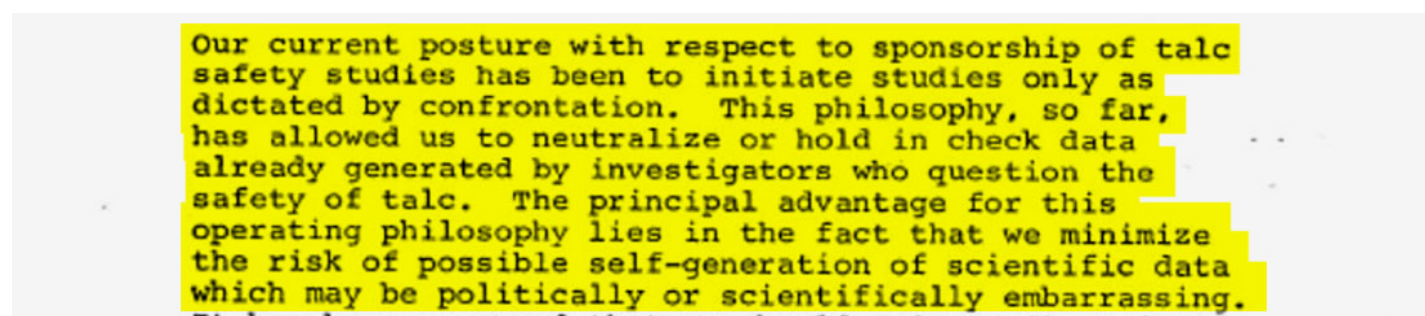
By [LISA GIRION](#)

Johnson & Johnson developed a strategy in the 1970s to deal with a growing volume of research showing that talc miners had elevated rates of lung disease and cancer: Promote the positive, challenge the negative.

That approach was summed up by a J&J applied research director in a “strictly confidential” March 3, 1975, memo to managers of the baby products division, which used the talc in J&J’s signature Baby Powder.

“Our current posture with respect to the sponsorship of talc safety studies has been to initiate studies only as dictated by confrontation,” the [memo](#) said. “This philosophy, so far, has allowed us to neutralize or hold in check data already generated by investigators who question the safety of talc.”

1973



A J&J executive laid out the company’s policy of countering negative research about the health effects of talc in a memo to managers.

Also, the memo said, “we minimize the risk of possible self-generation of scientific data which may be politically or scientifically embarrassing.”

J&J’s effort to protect its iconic Baby Powder franchise by shaping research was led by physician and scientist executives. An early 1970s study of 1,992 Italian talc miners shows how it worked: J&J commissioned and paid for the study, told the researchers the results it wanted, and hired a ghostwriter to redraft the article that presented the findings in a journal.

The effort entailed other attempts to influence research, including a U.S. government study of the health of talc workers in Vermont. J&J’s Windsor Minerals Inc subsidiary, one of several mine operators involved in the study, developed a relationship with the U.S. National Institute of Occupational Safety and Health researchers to “even influence the conclusions” through suggestions of “subjective interpretations,” according to a 1973 Windsor Minerals [memo](#).

Peter Bicks, outside counsel for J&J, told Reuters in an email that for the Vermont study, company “representatives acted in an ‘educational and advisory capacity’ to provide the researchers with a realistic study plan.”

A 1979 article in the Journal of Environmental Pathology and Toxicology detailing the findings of the study was not good news for talc. It reported a “significant increase” in “respiratory cancer mortality” among miners. A subsequent analysis of the underlying data published in 1988 determined that at least one of the workers died of mesothelioma, the cancer most closely associated with asbestos.

The proposal to study the health of miners of the Italian talc used in Baby Powder for decades came from William Ashton, J&J’s longtime talc supply chief. Ashton had obtained a summary of miners’ medical records compiled by an Italian physician, who also happened to control the country’s talc exports.

J&J should use those records “for maximum benefit,” Ashton said in a May 8, 1973, [letter](#) to Dr Gavin Hildick-Smith, J&J’s director of medical affairs. “It seems to me that the Italian records give us the opportunity to fortify a position on talc safety.”

At the time, the U.S. Food and Drug Administration was considering a limit on asbestos in talcs. In an Oct. 18, 1973, [memo](#), Hildick-Smith advised J&J: “The risk/benefit ratio of conducting an epidemiological study in these mines must be considered.”

By early 1974, the study was a go. Hildick-Smith sent money to the Italian talc exporter-physician to hire a team of researchers. Hildick-Smith told the lead researcher in a June 26, 1974, [letter](#) exactly what J&J wanted: data that “would show that the incidence of cancer in these subjects is no different from that of the Italian population or the rural control group.”

That is exactly what J&J got, Hildick-Smith told colleagues a few months later. At a meeting on Sept. 27, 1974, for a “Talc/powder Safety Studies Review,” he [reported](#) the Italian study would dispel the “cancer concern associated with exposure to talc.”

The following spring, Hildick-Smith got a draft of the Italian study from the lead researcher. It needed work to meet the “form and style” requirements of the target journal, he told colleagues in a March 31, 1975, [memo](#). He added that he would send it to a scientific ghostwriter “who will hold it in confidence and rewrite it.”

The article that appeared in 1976 in the Journal of Occupational and Environmental Medicine reported results even better than J&J had bargained for. The study found fewer lung cancer deaths than expected, a result that the authors said supported “the thesis of no cancerogenic effect attributable to pure talc.”

It also found no mesothelioma, the signature cancer of asbestos exposure. There is no evidence J&J manipulated or misused the data. Experts for plaintiffs have testified that the Italian study was too small to draw any conclusions about the incidence of such a rare cancer. J&J’s expert witnesses have concluded the opposite.

Bicks noted that the Italian study has been updated three times – in 1979, 2003 and 2017 – “confirming the lack of association between exposure to asbestos-free talc, lung cancer and mesothelioma.”

J&J got a lot of mileage out of the study. It was cited in a review article titled “The Biology of Talc,” published Nov. 1, 1976, in the British Journal of Industrial Medicine. In addition to dozens of published studies, the review cited unpublished research, including [one](#) experiment that used a doll as a proxy for infants and that supported the company’s position on the safety of talc. It didn’t disclose that J&J had commissioned the unpublished research.

The author of the review article concluded that the “concern that has been expressed about the possible health hazard from consumer exposure to cosmetic talc is unwarranted ... There is no evidence that its normal use poses a hazard to health.”

The author was Hildick-Smith, the J&J physician executive who had overseen the Italian study and played a key role in the company’s talc safety research. The article did not disclose his J&J connection, identifying him only as a Rutgers University clinical assistant professor. Hildick-Smith died in 2006.

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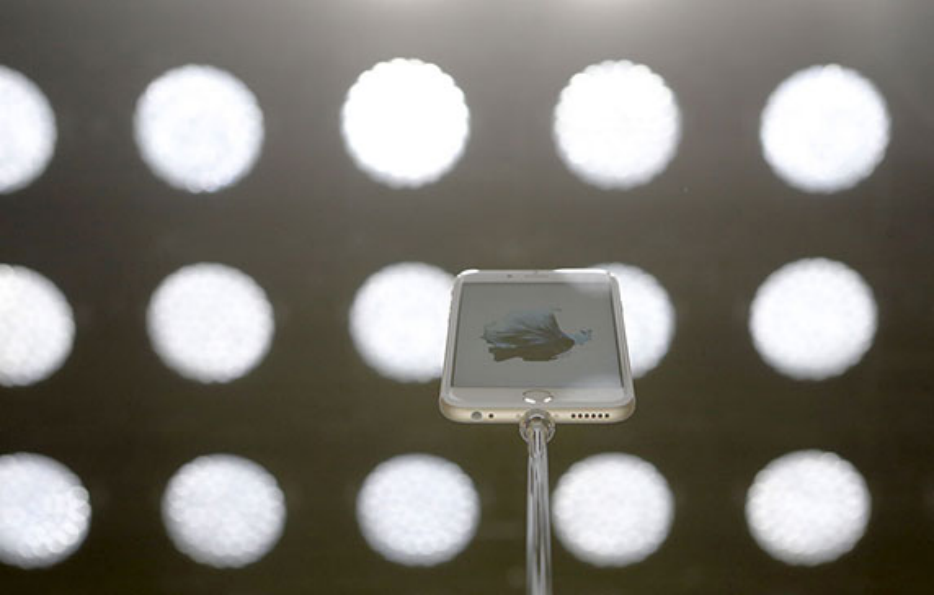
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